EPA REG. No 70127-6 Vol. 2

70127-6 and final printed labels

Susanne Cerrelli to: cdaniels 06/01/2012 01:42 PM

Dear Ms. Daniels,

Please read the attached PR notice.

There is a requirement that final printed labeling be submitted under 40 C.F.R. 156.10(a)(6), but there is also a little-known Pesticide Registration Notice (82-2, attached below) that clarifies this requirement.

You have indicated that the EPA Reg. No 70127-6 product has not been released for shipment, Please ask the registrant to certify this in writing, an email is acceptable (see example statements below)

Example Statements for Final Printed Labeling Requirement (May Vary Based Upon Your Situation)

"I certify that, since product X's registration on March 4, 2012, company X has not released product X for shipment; therefore, the requirement for submission of final printed labeling to EPA has not been triggered. Further, I acknowledge that, if company X decides to release product X for shipment in the future, final printed labeling will need to be provided to EPA prior to such action (in accordance with the terms of the xxx-xxx, 2012 registration notice)."

When you do send the final printed label, please address the following elements.

The 70127-6 label is missing net weight, batch code, expiration date (on page 1), and the agent needs to remove text on label that says "note to reviewer" (on page 4),

1 attachment

prnotice82-02.pdf

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

March 23, 2012

Sheryl Reilly, Ph.D.
Biopesticides and Pollution Prevention Division (7504P)
Office of Pesticide Programs
Document Processing Desk
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: Submission of Final Printed Label for Taegro Technical (EPA Reg. No. 70127-6)

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (Novozymes, EPA Company Number 70127, 5400 Corporate Circle, Salem, VA 24153), Exponent, Inc. is submitting a final printed label for the EPA registered product Taegro Technical (EPA Reg. No. 70127-6). The following documents are enclosed in support of this action:

- Application for Pesticide, EPA 8570-1 Form; and
- Final Printed Label (2 copies).

This submission is the final printed label in response to the notice of amended registration for this product from EPA dated April 26, 2011.

If you have any questions, please contact me via phone at (202) 772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.
Matthew Feinberg, Exponent, Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Sheryl Reilly	☒ None ☐ Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc. / Taegro Technical	PM# BPPD	

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals, Inc.
5400 Corporate Circle,
Salem, Virginia 24153

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 04-26-2011
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label in response to a letter from EPA dated 04-26-2011.

NOT REVIEWED in accordance with PR Notice 82-1 based on draft labeling dated 3/27/12

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
**Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	100 to 500 lbs.	☒ On Bag ☐ On Labeling accompanying product

6. Manner in Which Label Is Affixed to Product ☐ Lithograph ☒ Other Label is glued to plastic bag ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772 4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
BY: Dean Thome	Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome	5. Data: March 23, 2012

TAEGRO® Technical

NOT REVIEWED
In accordance with PR Notice 82-2
based on draft labeling dated

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

April 4, 2012

Sheryl Reilly, Ph.D.
Biopesticides and Pollution Prevention Division (7504P)
Office of Pesticide Programs
Document Processing Desk
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Submission of Final Printed Label for Taegro Technical (EPA Reg. No. 70127-6)**

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (Novozymes, EPA Company Number 70127, 5400 Corporate Circle, Salem, VA 24153), Exponent, Inc. is submitting a final printed label for the EPA registered product Taegro Technical (EPA Reg. No. 70127-6). The following documents are enclosed in support of this action:

- Application for Pesticide, EPA 8570-1 Form; and
- Final Printed Label (2 copies).

This submission is the final printed label in response to the notice of amended registration for this product from EPA dated March 27, 2012.

If you have any questions, please contact me via phone at (202) 772-4945 or via email at mfeinberg@exponent.com.

Sincerely,

Matthew Feinberg
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.
Carrie Daniels, Exponent, Inc.

NOT REVIEWED
in accordance with PR Notice 82-2
based on draft labeling dated 3/27/12

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 70127-6
2. EPA Product Manager: Sheryl Reilly
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): Novozymes Biologicals, Inc. / Taegro Technical
   PM# BPPD
5. Name and Address of Applicant *(Include ZIP Code)*

   Novozymes Biologicals, Inc.
   5400 Corporate Circle,
   Salem, Virginia 24153

   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
   EPA Reg. No.
   Product Name

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 03-27-2012
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label in response to a letter from EPA dated 03-27-2012.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
**Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: 100 to 500 lbs.
5. Location of Label Directions: ☒ On Bag ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☒ Other Label is glued to plastic bag ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Dean Thome
3. Title: Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome
5. Date: April 4, 2012

TAEGRO® Technical

NOT REVIEWED
In accordance with PR Notice 82-2
based on draft labeling dated

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store between 39°F (4°C) and 73 F (23°C), but do not exceed 95°F (35°C), and use within two years. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

Material Sent for Data Extraction

Reg. # 70127-6

Description: Label amendment

☐ Material(s) Sent to Data Extraction Contractors:

- ☑ New Stamped Label Dated 3/27/12
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☒ Decision #: 461702

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information, please call 703-605-0716.

Reviewer: Susanne Cerrelli

Phone: 308-8077 Division: BPPD

Date: 3/27/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 27 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Matthew Feinberg, Agent for Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington DC 20036

RE: Revised Label for Taegro Technical (EPA Reg. No. 70127-6)
OPP Decision Number: D461702

Dear Mr. Feinberg:

The Agency has reviewed your request to amend the Taegro Technical label to revise the Pesticide Storage instructions.

The Agency has reviewed the submitted "Final Storage Stability Study," MRID 48747701. BPPD has determined that these data for *Bacillus subtilis* Var. *amyloliquefaciens* FZB24 are acceptable to support the label amendment and demonstrate that this product is stable for a duration of 2 years when stored at a temperature range of 4-23°C.

The label amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit two (2) copies of the final printed labeling prior to releasing the product for shipment.

CONCURRENCES								
SYMBOL ►	7511P	7511P						
SURNAME ►	SGroff	Quilt						
DATE ►	3/23/12	3/27/12						

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

ACCEPTED
MAR 27 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.
70127-6

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store between 39°F (4°C) and 73 °F (23°C), but do not exceed 95° F (35°C), and use within two years. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

BPPD Label Amendment Checklist

Fast Track ☐ and PRIA Actions B650 ☐, B680 ☐, B681 ☐, B750 ☐, B890 ☐ &B900 ☐

EPA Reg. No.: **RAL:** **Application Date:**

#	Check list Item	Yes	No
1.	**Application Form** (EPA Form 8570-1) - signed & complete, including package type? **IF NO, STOP!** Call applicant and have them correct application and resubmit. 100-5001b bags	✓	
2.	**Final printed labeling** received for previous action? **IF NO, STOP!** E-mail applicant and request final printed labeling (FPL).		
3.	Does the registration notice have terms/conditions (ex: storage stability data)? Unconditional If so have the terms/conditions been met? ↳ Final printed labels? YES batch submitted + evaluated 3/21/11	593-L Sent in Mail	
4.	If new use sites are being added, are they subject to OPP's process for public involvement in pesticide registration actions? ☒ N/A		
5.	**Data and Data Matrix** present. (EPA Form 8570-35) NA ☐ If Fast Track, check to see if original registration supported by data, formulators exemption, etc.	✓	
a.	Using Selective Method? [**IF NO, SKIP to item 4 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.**]	✓	
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.	✓	
c.	Adequate product specific data?	✓	
d.	Registered source used for active ingredient? **IF YES, SKIP to ITEM 4.** (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) **If NO or if use not supported by registered source,** generic data is necessary.		✓
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?	✓	
f.	Public copy of Data Matrix provided? (PRN 98-5)	✓	
6.	**Certification with Respect to Citation of Data** present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA ☐	✓	
a.	Did applicant check a Method of Support?	✓	
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		✓
c.	Is the form signed and dated?	✓	
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources?		✓
	IF YES, is the required authorization letter included in application? NA ☐		
7.	**Label(s) Review** Note only 2 updates changed since last amendment approved **Date of Label Review:** 3-22-12		
a.	Label(s) in conformance with current *Label Review Manual* and appropriate REDS.		
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.	✓	
c.	Nominal concentration of active ingredient shown in ingredients statement.	✓	
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).	✓	
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).	✓	
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? **If YES**, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		✓

h.	Does label bear “National Organ rogram” (PR Notice 2003-1) or OMRI cl ?		
	If YES, National Organic Program or OMRI claims approved by Chris Pfiefer? NA ☐		
i.	Labeling is acceptable. Corrections or changes are NOT necessary.		
j.	Comments:		

Pages 23-24 - *Claimed confidential by submitter*

highlighted copy w/ change on page 4

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

ACCEPTED

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store between 39°F (4°C) and 73 °F (23°C), but do not exceed 95° F (35°C), and use within two years. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

Fee for Service {912012}~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

Receipt No. S- 912012

EPA File Symbol/Reg. No. 70127-6

Pin-Punch Date: 2/21/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B680

Granted: B680

Amount Due: $ 4631 (pd not due if fee waiver was requested)

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☒ Uncleared Inert in Product

Reviewer: Sheylla Reid / Alan Reynolds Date: 2/28/12

Remarks:

this is a RIA action -Alan Reynolds 2/28/12

If the storage stability study was a term or condition of registration, this is a non-PRIA (FT) amendment. I will have to check the

70127-6 Taegro Technical
Matthew Feinberg
to:
Susanne Cerrelli
03/23/2012 03:42 PM
Cc:
Carrie Daniels
Hide Details
From: Matthew Feinberg <mfeinberg@exponent.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Cc: Carrie Daniels <cdaniels@exponent.com>

1 Attachment

Novozymes - Submission of Final Printed Label for Taegro Technical.pdf

Ms. Cerrelli,

Please find attached a copy of the Final Printed Label submission for Taegro Technical (EPA Reg. No. 70127-6), submitted to document processing today, Friday, March 23rd. Please note that the Final Printed Label and the amended Master Label approved on April 26, 2011 are identical. If you have any questions or need anything further, please feel free to contact me.

Regards,

Matthew Feinberg
Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Tel. 202.772.4945
Fax 202.772.4979
mfeinberg@exponent.com

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1300
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

March 23, 2012

Sheryl Reilly, Ph.D.
Biopesticides and Pollution Prevention Division (7504P)
Office of Pesticide Programs
Document Processing Desk
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: Submission of Final Printed Label for Taegro Technical (EPA Reg. No. 70127-6)

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (Novozymes, EPA Company Number 70127, 5400 Corporate Circle, Salem, VA 24153), Exponent, Inc. is submitting a final printed label for the EPA registered product Taegro Technical (EPA Reg. No. 70127-6). The following documents are enclosed in support of this action:

- Application for Pesticide, EPA 8570-1 Form; and
- Final Printed Label (2 copies).

This submission is the final printed label in response to the notice of amended registration for this product from EPA dated April 26, 2011.

If you have any questions, please contact me via phone at (202) 772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.
Matthew Feinberg, Exponent, Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Sheryl Reilly	☒ None ☐ Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc. / Taegro Technical	PM# BPPD	

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals, Inc.
5400 Corporate Circle,
Salem, Virginia 24153

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 04-26-2011
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label in response to a letter from EPA dated 04-26-2011.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	100 to 500 lbs.	☒ On Bag ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Other Label is glued to plastic bag ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
BY: Dean Thome	Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome	5. Date: March 23, 2012

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

Complies with
EPA Accepted Labeling
Date: MAR 2 7 2012
Reviewer: S Cerulli

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

February 17, 2012

Dr. Sheryl Reilly, Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs, U.S. EPA (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Submission of EPA Pesticide Registration Improvement Act Information
U.S. EPA FIFRA Service Fees

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, Virginia 24153, EPA Company Number 70127), Exponent is submitting a Pesticide Registration Improvement Act Fee for the following amendment submission:

- Taegro Technical (EPA Reg. No. 70127-6), B680, $4,631, Pay.gov Tracking ID 255P1QD3, and Agency Tracking ID 74282232229.

This submission is for a label amendment classified as B680, label amendment requiring data submission, PRIA review time frame 4 months, and a fee of $4,631.

Should you have any questions regarding this submission, please contact me via telephone at 202-772-4945 or via email at mfeinberg@exponent.com.

Sincerely,

Matthew Feinberg
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.
Carrie Daniels, Exponent, Inc.

-----Original Message-----
From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]
Sent: Wednesday, February 15, 2012 8:51 AM
To: DNTM (Dean Thome)
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 255P1QD3
Agency Tracking ID: 74282232229
Transaction Type: Sale
Transaction Date: Feb 15, 2012 9:50:46 AM

Account Holder Name: Dean Thome
Transaction Amount: $4,631.00
Billing Address: 3935 Thatcher Avenue
City: Saskatoon
State/Province: Saskatchewan
Zip/Postal Code: 57R1A3
Country: CAN
Card Type: MasterCard
Card Number: **********6294

Decision Number:
Registration Number: 70127-6
Company Name: Novozymes Biologicals Inc
Company Number: 70127
Action Code: B680

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 3-21-12

Document Part Of: 70127-6
MRID, If Any: 487477

Content Screen: Recommended to Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

SHERYL REILLY

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 2-29-12 Release Date

Experts In-Processing Signature: MF Harrington Date 2-29-12 Fee Paid: Yes __

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number: 70127-6	EPA Receipt Date: 2-29-12

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	**no**			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)**(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Amendment Pass
PR. N. 11-03 Pass

I-6 MRID 47727-7

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. <u>All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.</u>

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 29, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-461702
EPA File Symbol or Registration Number: 70127-6
Product Name: TAEGRO TECHNICAL
EPA Receipt Date: 21-Feb-2012
EPA Company Number: 70127
Company Name: NOVOZYMES BIOLOGICALS, INC.

MATTHEW FEINBERG
EXPONENT, INC.
NOVOZYMES BIOLOGICALS, INC.
1150 CONN., AVE., N.W., SUITE 1100
WASHINGTON, DC 20036-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8715.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Please read Instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☒ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Sheryl Reilly	☒ None ☐ Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc. / Taegro Technical	PM# BPPD	

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, Virginia 24153

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of an amendment to revise the Label for Taegro Technical and to submit a new Storage Stability study.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	100 to 500 lbs.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Lebel is Affixed to Product ☐ Lithograph ☒ Other Label is glued to plastic bag ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Dean Thome	3. Title Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome	5. Date: February 15, 2012

Pages 49-50 - *Claimed confidential by submitter*

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Novozymes Biologicals, Inc. 5400 Corporate Circle, Salem, VA, 306-657-8238	EPA Registration Number/File Symbol 70127-6
Active Ingredient(s) and/or representative test compound/s† Bacillus subtilis var.amyloliquefaciens Strain FZB24	Date 02/17/2012
General Use Pattern/s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food use and non-food use	Product Name Taegro Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Dean Thome	02/17/2012	Dean Thome, Regulatory Affairs Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 1 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Final Storage Stability Study for Taegro Technical (70127-6)	New Submission	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1500,	Product Identification and Disclosure of Ingredients Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG.	44758101	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1200	Description of Beginning and Manufacturing Process Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG	44758102	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1200	Amended Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)	48311901	Novozymes Biologicals, Inc.	OWN	
885.1300	Discussion of the Formation of Impurities Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG	44758103	Novozymes Biologicals, Inc.	OWN	
885.1400	Lot Analysis of Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN23	44758104	Novozymes Biologicals, Inc.	OWN	
885.1400	5 Batch Analysis for Taegro Technical (70127-6)	48309801	Novozymes Biologicals, Inc.	OWN	
885.1500	Certification of Ingredient Limits: TAE-022 Technical, TAE-WDG	44758105	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1200, 885.1300, 885.1400, 885.1500	Responses to Question Raised Regarding MRID Numbers 44758102, 44758103, 44758104, and 44758105 TAE-022 Technical and WDG Bacillus subtilis var. amyloliquefaciens Strain FZB24	44976001	Novozymes Biologicals, Inc.	OWN	
830.6302, 830.6303, 830.6304, 830.7300, 830.7000	Determination of the Color, Physical State, Odor, pH, and Density of Bacillus subtilis var. amyloliquefaciens: TAE-022 Technical, TAE-WDG: Lab Project Number: 495C-101	44758106	Novozymes Biologicals, Inc.	OWN	
830.6317	Interim Storage Stability Study for Taegro Technical (70127-6)	48311902	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 2 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100, 885.1200, 885.1400	Response to Questions Raised Regarding MRID Numbers 4475102 and 4475104 TAE-022 Technical and WDG Bacillus subtilis var. amyloliquefaciens Strain FZB24.	44986501	Novozymes Biologicals, Inc.	OWN	
830.6302, 830.6303, 830.6304, 830.7300, 830.7000	Determination of the Color, Physical State, Odor, pH, and Density of Bacillus subtilis var. amyloliquefaciens End-Use Product: TAE-022 Technical, TAE-WDG: Lab Project Number: 495C-103.	44758107	Novozymes Biologicals, Inc.	OWN	
885.3050 (870.1100)	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, Following Acute Oral Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN2	44758108	Novozymes Biologicals, Inc.	OWN	
885.3050 (870.1100)	Acute Toxicity/Limit Testing of Bacillus subtilis var. amyloliquefaciens, Strain FZB24, WDG End Use Product, Following Acute Oral Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN8.	44758109	Novozymes Biologicals, Inc.	OWN	
885.3100 (870.1200)	Acute Dermal Toxicity/Pathology Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN5	44758110	Novozymes Biologicals, Inc.	OWN	
885.3100 (870.1200)	Acute Dermal Toxicity/Pathology Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, WDG End Use Product in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN10	44758111	Novozymes Biologicals, Inc.	OWN	
885.3150 (870.1300)	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, Acute Intratracheal Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN3.	44758112	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

EPA Form 8570-35 (V-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy
Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 3 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Tacgro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3200	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens. Strain FZB24, Following Acute Intravenous Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN4.	44758113	Novozymes Biologicals, Inc.	OWN	
870.2400	Primary Eye Irritation Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN6	44758114	Novozymes Biologicals, Inc.	OWN	
870.2400	Primary Eye Irritation Study of Bacillus subtilis var. amyloliquifaciens. Strain FZB24, WDG End Use Product in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN11.	44758115	Novozymes Biologicals, Inc.	OWN	
885.3400	Hypersensitivity Incidents Report Bacillus subtilis var. amyloliquifaciens Strain FZB24: TAE-022 Technical, TAE-WDG.	44758116	Novozymes Biologicals, Inc.	OWN	
885.3400	Sensitivity of Detection of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, for Toxicity/Pathogenicity Testing in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743SN1.	44758120	Novozymes Biologicals, Inc.		
870.2600	Dermal Sensitization Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24 in Guinea Pigs Using the Buehler Method: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN7	44758117	Novozymes Biologicals, Inc.	OWN	
NA	Potential Health Effects of Bacillus subtilis var. amyloliquifaciens Strain FZB24 A Review of Literature: TAE-022 Technical, TAE-WDG.	44758118	Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 4 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Growth Parameters of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, at Various Temperatures: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN25	44758119	Novozymes Biologicals, Inc.	OWN	
885.4050	Bacillus subtilis var. amyloliquifaciens: An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite: TAE-022 Technical, TAE-WDG: Lab Project Number: 495-101.	44758121	Novozymes Biologicals, Inc.	OWN	
885.4200	Bacillus subtilis var. amyloliquifaciens: A Five-Concentration Toxicity and Pathogenicity Test with the Rainbow Trout (Oncorhynchus mykiss): TAE-022 Technical, TAE-WDG: Final Report: Lab Project Number: 495A-102.	44758123	Novozymes Biologicals, Inc.	OWN	
885.4240	Bacillus subtilis var. amyloliquifaciens: A 21-Day Life-Cycle Toxicity and Pathogenicity Test with the Cladoceran (Daphnia magna): TAE-022 Technical, TAE-WDG: Final Report: Lab Project Number: 495A-101.	44758122	Novozymes Biologicals, Inc.	OWN	
885.4300	Algae Growth Inhibition Test--Test Article Bacillus subtilis Strain FZB24: TAE-022 Technical, TAE-WDG: Lab Project Number: 83-00-0551-00-93	44758127	Novozymes Biologicals, Inc.	OWN	
885.4380	Evaluation of the Dietary Effect(s) of Bacillus subtilis var. amyloliquifaciens on Honey Bee Larvae (Apis mellifera L.): TAE-022 Technical, TAE-WDG: Lab Project Number: CAR 167-98.	44758124	Novozymes Biologicals, Inc.	OWN	
885.4380	Evaluation of the Dietary Effect(s) of Bacillus subtilis var. amyloliquifaciens on Adult Honey Bees (Apis mellifera L.): TAE-022 Technical, TAE-WDG: Lab Project Number: CAR 169-98.	44758125	Novozymes Biologicals, Inc.	OWN	
NA	Bacillus subtilis var. amyloliquifaciens Strain FZB 24: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate: TAE-022 Technical, TAE-WDG: Lab Project Number: 495-102.	44758126	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 1 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 2 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy
Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 3 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.		
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: February 17, 2012			EPA Reg No./File Symbol 70127-6		Page 4 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome, Regulatory Affairs Manager		Date 02/17/2012

Material to be added to an e-Jacket/Jacket

Reg. No. 70127-6

1. ☐ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

_____

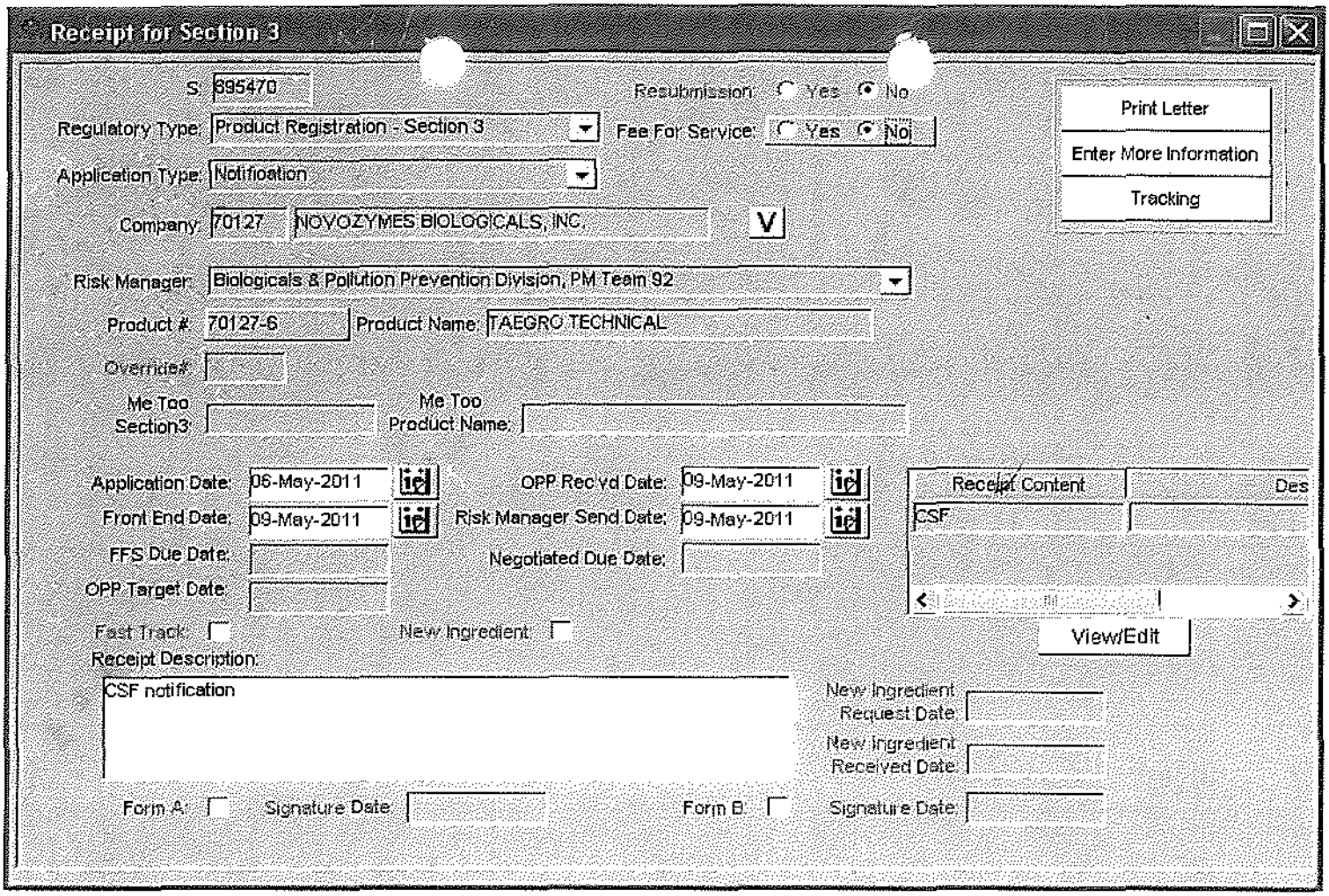
_____

2. ☐ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification – Accepted – to add minor change
   - ☐ New CSF
   - ☐ Other:

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Mary Paden
Phone: (703) 308-0411 Division: BPPD
Date: 09/16/2011

Created January 26, 2009



Marx

332 : Notification

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

May 6, 2011

Dr. Sheryl Reilly, Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs, U.S. EPA (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Notification per PR Notice 98-10 for Taegro Technical (EPA Registration No. 70127-6)

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, Virginia 24153, EPA Company Number 70127), Exponent is submitting a notification of per PR Notice 98-10 for the registered product Taegro Technical (EPA Registration No. 70127-6), containing the active ingredient *Bacillus subtilis* var. *amyloliquefacies* Strain FZB24. The following items are enclosed in support of this notification:

- Transmittal Document;
- Application for Registration (EPA Form 8570-1); and
- MSDS for [redacted]

[redacted]

A copy of the MSDS for this ingredient is included for your reference. This ingredient is comprised completely of the [redacted]

Manufacturing process information may be entitled to confidential treatment

We have not submitted a new confidential statement of formula or a label for this notification, because no changes have been made to the confidential statement of formula on file with EPA or the label previously approved by EPA.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions regarding this submission, please contact me via telephone at 202-772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 70127-6
2. EPA Product Manager: Sheryl Reilly
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): Novozymes Biologicals, Inc. / Taegro Technical
   PM# BPPD
5. Name and Address of Applicant *(Include ZIP Code)*:
   Novozymes Biologicals, Inc.
   5400 Corporate Circle,
   Salem, Virginia 24153
   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No.
   Product Name

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☐ Other - Explain below.

Notification Accepted

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of a notification per PR Notice 98-10 Taegro™ Technical (EPA Reg. No. 70127-6).

Date: 07/07/2011
Reviewer: Mary S. Poulin

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
**Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: 8.8oz., or 13.2oz., or 1lb. 10.5oz.
5. Location of Label Directions: ☒ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☒ Other Label glued on plastic bag. ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Dean Thome
3. Title: Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome
5. Date: May 6, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, NW, Suite 1100
Washington, DC 20036

RE: Product Name: Taegro Technical
EPA Reg. No: 70127-6
Notification Dated: May 6, 2011 to [redacted] per PRN 98-10.

Dear Ms Daniels:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as **"Notification Accepted"** and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at paden.mary@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

SEP 02 2011

CONCURRENCES								
SYMBOL ▶	7511(P)							
SURNAME ▶	Paden							
DATE ▶	02SEP11							

Pages 66-70 -*Product ingredient source information may be entitled to confidential treatment*

Inert ingredient information may be entitled to confidential treatment

Re: FW: Inert ingredient - Novozymes (70127-6)
John Kough to: Carrie Daniels 09/02/2011 09:02 AM
Cc: Sheryl Reilly, Mary Paden

Carrie,

I have spoken with Sheryl Reilly and your action seems to fall under the notification criteria as a minor amendment for the manufacturing process of Taegro (EPA reg. no. 70127-6) where you are [redacted]

I understand form the email chain that [redacted]

Thanks for your help and have a good Labor Day if I don't hear from you before then.

John Kough
703-308-8267

"Carrie Daniels" Hi John, 09/01/2011 03:56:27 PM

From: "Carrie Daniels" <cdaniels@exponent.com>
To: John Kough/DC/USEPA/US@EPA
Date: 09/01/2011 03:56 PM
Subject: FW: Inert ingredient - Novozymes (70127-6)

Hi John,

Thank you again for your time today to discuss the inert ingredient [redacted] in Novozyme's Taegro product (EPA Registration number 70127-6).

Per our discussion, I am forwarding the email that I sent to PV with supporting information for the inert ingredient and I have attached an email from Sandra Rock in the inerts group with approval for this product under 40 CFR Part 180.960 (I have also forwarded that approval email to Mary Paden).

Should you need additional information in your discussions with Sheryl Reilly and Mary Paden regarding our notification request, please do not hesitate to contact me via email or telephone.

Sincerely,
Carrie

Senior Managing Regulatory Consultant
Exponent, Inc.
Tel. 202.772.4916
cdaniels@exponent.com

From: Carrie Daniels
Sent: Thursday, September 01, 2011 11:00 AM
To: Pv Shah

Inert ingredient information may be entitled to confidential treatment

Cc: Paden.Mary@epamail.epa.gov; Reilly.Sheryl@epamail.epa.gov
Subject: Inert ingredient

Dear PV,

I am following up on our conversation last week (8/23) regarding the inert ingredient [redacted], which consists of [redacted]
As we discussed, this CAS number is exempt from tolerance under [redacted]

I have attached the M5DS, and two emails from [redacted] the supplier of this material, which indicate that [redacted]

Can you please confirm that based on the attached information the inert ingredient of interest is acceptable for use in a food use pesticide?

Thank you again for your time and assistance with this question.

Sincerely,
Carrie Daniels

Senior Managing Regulatory Consultant
Exponent, Inc.
Tel. 202.772.4916
cdaniels@exponent.com

----- Message from [redacted] > on Tue, 3 May 2011 12:20:48 -0700 -----

To: "Carrie Daniels" <cdaniels@exponent.com>

Subject: RE: [redacted]

Carrie,

This is to confirm that [redacted]

Best regards,

Pages 73-77 – * Product ingredient source information may be entitled to confidential treatment*

MATERIAL TO BE ADDED TO JACKET

REG # 70127-6

Description: D443036

Amendment letter signed 4/26/11

if applicable, check all that are attached		
☑	new stamped accepted label	Send to CSC
☑	new CSF	
☐	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer's Name: Suzanne Carroll Date: 5/3/11

Phone: 703-308-8077 Division: BPPD

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

ACCEPTED
APR 26 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70127-6

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

7. Revising text in the Agricultural Use Requirement box of the Taegro label.

For both products the new basic CSFs dated April 19, 2011 supersede all of the previous basic CSFs and will be filed in the Agency's records as the official basic CSFs for the above listed products.

The amendments referred to on the previous page, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit two (2) copies of the final printed labeling prior to releasing the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA § 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any further questions regarding this, please do not hesitate to contact Susanne Cerrelli, at 703-308-8077 (cerrelli.susanne@epa.gov), or me at 703-308-8269 (reilly.sheryl@epa.gov).

Sincerely,

for

Sheryl K. Reilly, Ph.D.
Chief
Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch (7511P)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9 ~~73.3~~ %
OTHER INGREDIENTS	20.1 ~~26.7~~ %
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662
~~www.novozymes.com~~

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001 ~~-010~~
Made in the U.S.A.

~~Not for sale or use after: [Date to be inserted]~~
Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor ~~for further~~ immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. ~~Do not freeze or expose to temperatures above 80 F. Close opened packages tightly. Store in a cool, dry place and use within one year.~~ Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer bag and for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

~~[Note to reviewer: The "Not for sale or use after (date)" is to serve as the batch code.]~~
[Note to reviewer: This product is sold in large plastic bags contained ~~in cardboard frames~~ within cardboard boxes.]

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear such as goggles, face shield or safety glasses, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Taegro
Carrie Daniels
to:
Susanne Cerrelli
04/21/2011 03:57 PM
Cc:
"DNTM (Dean Thome)"
Show Details

Hi Susanne,

Per our conversation, Novozymes has not sold or distributed the Taegro products (EPA Registration Numbers 70127-S and 70127-6) and, therefore, there are no final printed labels available at this time.

Regards,
Carrie

Senior Managing Regulatory Consultant
Exponent, Inc.
Tel. 202.772.4916
cdaniels@exponent.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☒ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 70127-6
2. EPA Product Manager: Sheryl Reilly
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): Novozymes Biofogicals, Inc. / Taegro Technical
   PM# BPPD
5. Name and Address of Applicant *(Include ZIP Code)*

   Novozymes Biologicals, Inc.
   5400 Corporate Circle
   Salem, Virginia 24153

   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

Section II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of a 90-day amendment to revise the CSF and Label for Taegro Technical and to submit a new Manufacturing Process.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plastic Bag
**Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: 100 to 500 lbs.
5. Location of Label Directions: ☒ On Label ☐ On Labelling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☒ Other Label is glued to plastic bag ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Dean Thome
3. Title: Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome
5. Date: April 15, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 1 2 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Carrie Daniels, Agent for Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington DC 20036

RE: Revised Manufacturing Processes, Confidential Statements of Formulas (CSFs) and Labels for Taegro (EPA Reg.No. 70127-5) and Taegro Technical (EPA Reg.No. 70127-6)
OPP Decision Numbers: D443035 and D443036

Dear Ms. Daniels:

The Agency has completed its review of the referenced revised manufacturing processes, Confidential Statements of Formulas (CSFS), and labels for the above mentioned products. The manufacturing processes were determined to be Upgradable.

Below are the items that must be addressed before the amendments can be finalized:

1. The 8570-1 forms submitted with the above mentioned applications did not report the packaging used for each product. Please provide a complete 8570-1 with the packaging indicated for each package size sold for both products. This information is needed to evaluate the container disposal text.

2. There is no record that final printed labels were ever submitted following the registration of these products. Since this is a required term of registration, you must submit the final printed labels at this time.

3. The following changes need to be made to your Confidential Statement of Formulas for both products listed above:

a. [redacted] if any should be listed on a separate line on the CSF.

b. The minimum guaranteed CFU/g appears to be listed on the CSFs. The CFU/g listed on the label does not agree with that listed on the CSF.

Manufacturing process information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Numbers: D443035 and D443036
EPA File Registration Numbers: 70127-5 and 70127-6
Product Names: Taegro and Taegro Technical
EPA Receipt Date: December 13, 2010
EPA Company Number: 70127
Company Name: Novozymes Biologicals, Inc.

Carrie Daniels, Agent for Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington DC 20036

Subject: Revised Manufacturing Processes, Confidential Statements of Formulas (CSFs) and Labels

Dear Ms. Daniels:

The Agency has completed a review of the submitted revised manufacturing processes, Confidential Statements of Formulas (CSFS) and labels for the above mentioned products. The manufacturing processes were determined to be "Upgradable".

Below are the items that must be addressed.

1. The 8570-1 forms submitted with the above mentioned applications did not report the packaging used for each product. Please provide a complete 8570-1 with the packaging indicated for each package size sold for both products. To evaluate the container disposal text this information is needed.

2. There is no record that the final printed labels were ever submitted. Please submit your existing Final printed labels for our file records.

3. The following changes need to be made to your Confidential Statement of Formulas for both products listed above.

a. [redacted] if any should be listed on a separate line on the CSF.

CONCURRENCES								
SYMBOL ►	7511P	7511P						
SURNAME ►	S Leonard	SKN						
DATE ►	4-7-11	4/12/11						

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

edits on p-1 need to be made

b. The minimum guaranteed CFU/g appears to be listed on the CSFs. The CFU/g listed on the label does not agree with that listed on the CSF.

The following changes need to be made to your Taegro Technical label.

On page 1

1. Insert a summation line underneath 12.2%.

2. The minimum guaranteed CFU/g needs to be listed in the ingredient statement, and this number needs to be identical to the minimum guaranteed CFU/g that appears to be listed on the CSF. [Eg. "Contains a minimum of 2.0×10^{11} Colony forming units (CFU)/g."]

3. Correct the typographical error for "Expiry" and replace it with "Expiration" if that is the intended word.

4. Insert "such as goggles, face shield or safety glasses" after "protective eyewear," in the paragraph at the end of page 1.

On page 4

1. There is mention of Cardboard frames. How are these disposed of? Are these reused? Does Novozymes collect them? The disposal section needs to address all the packagingof the product. Also if a variety of packaging is used the disposal statements should address each type of package offered for sale.

The following changes need to he made to your Taegro label.

On page 1

1. Insert a summation line underneath 87.0 %.

2. The minimum guaranteed CFU/g needs to be listed in the ingredient statement, and this number needs to be identical to the minimum guaranteed CFU/g that appears to be listed on the CSF. [Eg. "Contains a minimum of 1.0×10^{10} Colony forming units (CFU)/g."]

3. Correct the typographical error for "Expiry" and replace it with "Expiration" if that is the intended word.

Page 4, in the Agricultural use Requirements box:

1. As required under 40 CFR 156.208 (c) (2) (ii) for products with Acute Toxicity Category II the Restricted Entry Interval needs to be changed to 24 hours.

2. Replace "*PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plant, soil, or water), is:*" with :
"For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear:"

On page 5:

1. In the paragraph that states "*Taegro is a fungicide used for suppressing selected soil born diseases such as rhizoctonia and Fusarium ... turf*" remove the words *"such as."* If there are other soil born diseases supported by product performance data, the applicant may add them but the term "such as" is vague and may be misinterpreted. In addition, the applicant may wish to add the common names of the pest listed: *Rhizoctonia* and *Fusarium* to inform the general public.

On page 10:

The use directions mention using 1 gram of Taegro, but no information was provided that indicates that the product is packaged in 1 gram packets. Clarification is requested.

In accordance with 40 CFR 152.105, if the Agency determines that an application is incomplete or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies and allow the applicant 75 days to make corrections. You must address and submit the deficient information outlined in this letter within 75 days of the date of this letter or EPA will administratively withdraw your application from further consideration without notice to you. Alternatively, you may choose to withdraw your application and resubmit a new application with the deficiencies addressed.

Please note that if you cannot quickly address the items listed above, the current PRIA due date of April 28, 2011 will need to be renegotiated to allow enough time for BPPD to conduct its review and make a regulatory decision, because approval of the submitted data cannot proceed until the above listed deficiencies are addressed.

Should you have any questions concerning this letter, please contact Susanne Cerrelli at 703-308-8077.

Sincerely,

Sheryl K. Reilly, Ph.D.
Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)

BPPD Formulation Amendment Check List

Fast Track ☐ and PRIA Actions B680 ☑, B681 ☐, B730 ☐

EPA Reg. No.: 70127-6 **RAL:** **Application Date:** 12/10/11

#	Check list Item
1.	**Application Form** (EPA Form 8570-1) - signed & complete including package type? **IF NO, STOP!** Call applicant and have them correct application and resubmit. yes but not complete
2.	**Final printed labeling** received for previous action? **IF NO, STOP!** E-mail applicant and request final printed labeling. NO
3.	Does the registration notice have terms/conditions (ex: storage stability data)? If so have the terms/conditions been met? 5 batch analysis → submitted Final printed labels → not available Not in packet either
4.	**Confidential Statement of Formula** (CSF) EPA Form 8570-4 Basic Formula ☑ Alternate Formula(s) ☐ ___
a.	CSF Review completed? **IF YES, SKIP to next item.** yes
b.	CSF is signed and dated? **IF NO, CALL APPLICANT.**
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?
d.	Are the totals accurate?
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).
f.	Viability (if live microbial, i.e., cfu/gram)? NA ☐
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?
h.	List 1 inert ingredient(s) present in the formulation?
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs. NA ☐
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? **If YES**, RAL must evaluate label directions for compliance with 40 CFR 180.1071. NO
5.	**Data and Data Matrix** present. (EPA Form 8570-35)
a.	a) Using Selective Method? [[**IF NO, SKIP to item 5 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.**]] yes
b.	Complete Data Matrix. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label. yes
c.	Adequate product specific data submitted? Comments @ CSF + Label

d.	Registered source used for active ingredient? **IF YES, SKIP to ITEM 5.** (Active ingredient is from a registered source and generic data should be satisfied by registered source. **IF NO**, generic data needed.	yes
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?	yes
f.	Public copy of Data Matrix provided? (PRN 98-5)	yes
6.	**Certification with Respect to Citation of Data** (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, a Certification with Respect to Citation of Data form is not needed. This is often true for minor amendments.]	
a.	Did applicant check a Method of Support?	yes
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	no
c.	Is the form signed and dated?	yes
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?	no
	IF YES, is the required authorization letter included in application? NA ☒	
7.	**Formulators Exemption** (EPA Form 5870-27)	
a.	If registrant is using a registered source active ingredient in the formulation, is form filled out completely and signed? NA ☒	
8.	**Science Review** completed? Comments: CSF + Label affect acceptability of data CFU/g need to agree w/ min	

Label Review

File Symbol: 70127-6 **Date:** 4/6/11 **Reviewer:** S Cavell

[Site/Use]	[Res /Ag /Both] [Food /Non-Food /Both]
[Tox Categories:]	[AcOral: 3 /AcDerm: 3 /AcInhl: 3 /EyeIrr: 2 /SkinIrr: 2 DermSens: -]

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide	----------	----------	X		Ch 6
Product Name	✓				Pg 12-3
Compny Name and Info	✓				Pg 15-1
Identification Numbers	✓				Ch 14
Net Contents	?				Ch 17
Ingredients Statement		X		→ Minimum CFR + ability	Ch 5
Label Claims			X		Pgs 4-5, 5-7 11-10 & Ch 12
Alternate Formula			X		5-12

Precautionary Statements

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC	✓				3-1 & 9 7-3 & 4
Signal Word	✓				Ch 3 Ch 7 Ch 10
General Heading >PRECAUTIONARY STATEMENTS=	✓			→ wear protective eyewear such as ..... safety glasses	Ch 7
First Aid (PRN 20001-1)	✓				Ch 3 & 7
Hazards to Humans and Domestic Animals		Still review			Ch 3, 7-3
PPE (WPS) Engineering Controls			X		Ch 7, Pg 7-12 Pgs 10-4, 15
User Safety Requirements			X		Ch 10
User Safety Recommendations			X		Ch 10
Environmental Hazards	✓				Ch 8
Physical and Chemical Hazards			✓		Pg 3-4 Ch 9

Directions for USE (FIFRA Text, WPS plus Storage and Disposal					
Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
Header >Directions for Use=	✓				10-16
Violation of Federal Law text	✓				10-26, 11-7
WPS Text (PPE)			X		Ch 10, 7-1 7-11
Non-WPS Text			X		7-12, Ch 10
Storage and Disposal	?			Could Board Examiner? how were they supposed of? Are they required?	11-16, Ch 13

Directions for Use (General Instructions and Information)					
Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
General Instructions and Sub-Header			X		
Chemigation / Prohibition			X		PRN
REI			X		Pg 10-20

Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
General Info. (non-site specific info. on uses, pests, mixing, and loading, tank mixing, etc.)	OK				
General Precautions and Restrictions			X		
Directions for Use					
Directions for Application			X		
Warranty Information					
Consistency with label instructions			X		12-6
Not false or misleading		X		needs qualifiers removes legal rights	

"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, ato the extent allowable by state lawe, or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or if jury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	87.8%
OTHER INGREDIENTS	12.2%
Total	100.0%

*Contains 5.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiry Date: [Batch code and expiry date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and

before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Note to reviewer: This product is sold in large plastic bags contained in cardboard frames.]

TAEGRO® Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	87.8%
OTHER INGREDIENTS	12.2%
Total	100.0%

*Contains 5.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

Batch code and Expiry Date: [Batch code and expiry date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING – Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and

before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE
TAEGRO consists of living microbes. Store at room temperature, but do not exceed 95° F (35°C), and use within one year. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL
Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Note to reviewer: This product is sold in large plastic bags contained in cardboard frames.]

Suzanne Cerulli

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 1-3-11

Document Part Of: 70127-6
MRID, If Any: 483119

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Document returned to:

SHERYL REILLY

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 12-13-10 Release DATE

Experts In-Processing Signature: MF HARRINGTON Date 12-13-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: 70127-6	EPA Receipt Date: 12-13-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label** (link to **http://www.epa.gov/oppfead1/labeling/lrm/**) **(Electronic labels on CD are encouraged and guidance is available)**(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

studies passed 86-5 review
Inerts approved for food use under 40 cfr 180.920, preharvest

JB
12/15/10

MRID 483119

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

November 30, 2010

Dr. Sheryl Reilly, Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs, U.S. EPA (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Submission of a 90-day Amendment for a revised CSF, Label, and Manufacturing Process for Taegro Technical (EPA Registration No. 70127-6)

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, Virginia 24153, EPA Company Number 70127), Exponent is submitting an amended basic Confidential Statement of Formula (CSF) and product label, amended manufacturing process and a interim storage stability study for the product Taegro Technical, (EPA Registration No. 70127-6), containing the active ingredient *Bacillus subtilis* var. *amyloliquefacies* Strain FZB24. The following items are enclosed in support of this 90-day amendment:

- Transmittal Document;
- Application for Registration (EPA Form 8570-1);
- Revised Basic Confidential Statement of Formula (2 copies);
- Copy of Previously Approved Basic Confidential Statement of Formula;
- Data Matrix (Public and Private versions);
- Certification with Respect to Data Citation (EPA Form 8570-34);
- Five copies of the revised master label (one with changes highlighted);
- Amended manufacturing process; and
- Interim storage stability study.

The manufacturing process for Taegro Technical has been amended in three specific places and these amendments are described in detail in the enclosed "Amended Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)." Novozymes initiated this change in the manufacturing process because the new process is more efficient and allows for more material to be manufactured at one time. Novozymes has amended the fermentation medium, changed the drying process used in the production process, and amended the certified limits for the product.

These changes and their impact on Taegro Technical and the final end-use product, Taegro (EPA Registration No. 70127-5) are explained in the confidential section of the Amended Description of Beginning Materials and Manufacturing Process.

In addition to the revised manufacturing process, a new storage stability study is being conducted to demonstrate that the change in the manufacturing process has not affected the stability of the product. The study is on-going, however, Novozymes is submitting an interim report at this time, showing that there is no affect on the stability of Taegro Technical under the new manufacturing process.

The product label and CSF have been revised to reflect the changes made in the manufacturing process. The percent by weight of the active ingredient has been revised on the label and CSF, however, the nominal activity of the active ingredient, as expressed in colony forming units (CFUs)/gram, has not changed. Novozymes has slightly revised the upper and lower limits. This new Basic CSF dated November 19, 2010 will supersede the previous Basic CSF on file with the Agency.

Novozymes has conducted a new five-batch analysis, as required on the most recent stamped approved label for Taegro Technical, dated January 22, 2010. This 5-batch analysis study is being submitted under separate cover in response to the registration requirement, and the information in this study confirms that the revised process meets the specifications on the new CSF submitted here.

Should you have any questions regarding this submission, please contact me via telephone at 202-772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153

CONTACT PERSON (Return to)

Carrie Daniels
Exponent, Inc.
1150 Connecticut Ave., N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Submission of a 90-day amendment for a revised CSF, Label, Manufacturing Process, and Stability Study for Taegro Technical (EPA Registration No 70127-6).

SUBMITTAL DATE:

November 30, 2010

Volume	Study Title	MRID No.
1	Administrative Package	
2	Amended Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)	
3	Interim Storage Stability Study for Taegro Technical (70127-6)	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 7, 2010

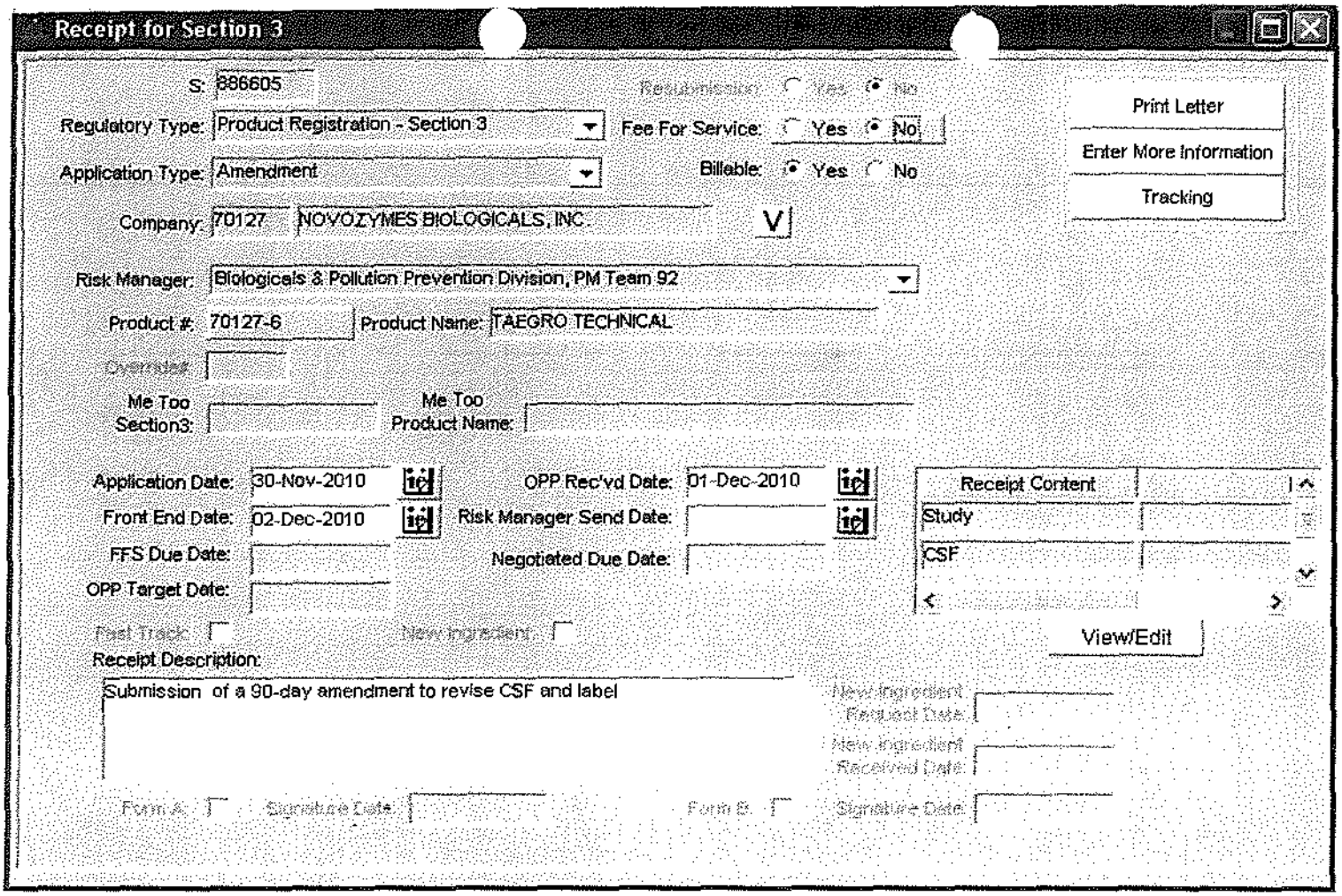
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

EXPONENT, INC.
NOVOZYMES BIOLOGICALS, INC.
1150 CONN., AVE., N.W., SUITE 1100
WASHINGTON, DC 20036-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-DEC-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 886605
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 70127 NOVOZYMES BIOLOGICALS, INC
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92
Product #: 70127-6
Product Name: TAEGRO TECHNICAL
Me Too Section3:
Me Too Product Name:
Application Date: 30-Nov-2010
OPP Rec'vd Date: 01-Dec-2010
Front End Date: 02-Dec-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Submission of a 90-day amendment to revise CSF and label
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 13, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-443036
EPA File Symbol or Registration Number: 70127-6
Product Name: TAEGRO TECHNICAL
EPA Receipt Date: 01-Dec-2010
EPA Company Number: 70127
Company Name: NOVOZYMES BIOLOGICALS, INC.

CARRIE DANIELS
EXPONENT, INC.
NOVOZYMES BIOLOGICALS, INC.
1150 CONN., AVE., N.W., SUITE 1100
WASHINGTON, DC 20036-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-7973.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2522H2GN
Agency Tracking ID: 74157951512

Account Holder Name: Dean Thome
Transaction Type: Sale
Transaction Amount: $4,631.00
Billing Address: 3935 Thatcher Avenue
City: Saskatoon
State/Province: Saskatchewan
Zip/Postal Code: S7R1A3
Country: CAN
Card Type: Master Card
Card Number: **********6294
Transaction Date: Dec 7, 2010 2:26:11 PM

Decision Number:
Registration Number: 70127-6
Company Name: Novozymes Biologicals Inc
Company Number: 70127
Action Code: B680

----- Message from "DNTM (Dean Thome)" <DNTM@novozymes.com> on Mon, 13 Dec 2010 07:38:37 -0800 -----

To: "Carrie Daniels" <cdaniels@exponent.com>

Subject: FW: Pay.Gov Payment Confirmation

-----Original Message-----
From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]
Sent: Tuesday, December 07, 2010 1:23 PM
To: DNTM (Dean Thome)
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2522H24C
Agency Tracking ID: 74157951117

Account Holder Name: Dean Thome
Transaction Type: Sale

Transaction Amount: $4,631.00
Billing Address: 3935 Thatcher Avenue
City: Saskatoon
State/Province: Saskatchewan
Zip/Postal Code: S7R1A3
Country: CAN
Card Type: Master Card
Card Number: ************6294
Transaction Date: Dec 7, 2010 2:23:12 PM

Decision Number:
Registration Number: 70127-5
Company Name: Novozymes Biologicals Inc
Company Number: 70127
Action Code: B680

RE: RESPONSE REQUIRED BY 12/15/10: Proof of PRIA fee payment required for amendments to EPA registration numbers 70127-5 (Taegro) and 70127-6 (Taegro Technical)

Carrie Daniels to: Teresa Downs 12/13/2010 10:43 AM

Dear Ms. Downs,

Attached are the receipts for Novozymes' payment of the two PRIA fees indicated below. Should you have any questions, please do not hesitate to contact me.

Sincerely,
Carrie Daniels

Managing Regulatory Consultant
Exponent, Inc.
Tel. 202.772.4916
cdaniels@exponent.com

-----Original Message-----
From: Downs.Teresa@epamail.epa.gov [mailto:Downs.Teresa@epamail.epa.gov]
Sent: Tuesday, December 07, 2010 12:27 PM
To: Carrie Daniels
Subject: RESPONSE REQUIRED BY 12/15/10: Proof of PRIA fee payment required for amendments to EPA registration numbers 70127-5 (Taegro) and 70127-6 (Taegro Technical)

Dear Ms. Daniels:

The Biopesticide Division's PRIA team has identified both of the above actions as subject to action code B680. Please email me a separate pay.gov receipt or a copy of a separate check in the amount of $4,631 as proof of fee payment for each action.

Section 33(B)(2(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received these actions on 12/1/10. If proof of fee payment is not received by COB on 12/15/10, then we will reject these actions for non-payment of the PRIA fee and send you an invoice for
$2,316 (25% of the $4,631 fee x 2 actions). The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact Brian Steinwand at (703)305-7973.

I have included below some basic payment and small business fee waiver information from our website. For further information, please see:
http://www.epa.gov/pesticides/regulating/fees/index.htm

ONLINE PAYMENT

To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, under "Find Public Forms":

Payment prior to and at application

- select "search by form name";
- on the A-Z Index of Forms page, select "P";
- from the list of forms on the first page, select "Pesticide Registration Act - Prepayment";
- complete the form entering the PRIA fee category and fee;
- keep a copy of the pay.gov acknowledgement of payment and attach a copy to the front of the application to assure that EPA can match the application with the payment; and
- submit the application.

PAYMENT BY CHECK

The Agency has established procedures for the submission of checks via certified mail, registered mail, or courier service. Checks should be made payable to USEPA or Environmental Protection Agency.

Note: Received checks will be converted into an electronic funds transfer (EFT). This means we will copy your check and use the account information on it to electronically debit your account for the amount of the check. The debit from your account will usually occur within 24 hours, and will be shown on your regular account statement.

You will not receive your original check back. We will destroy your original check, but we will keep the copy of it. If the EFT cannot be processed for technical reasons, you authorize us to process the copy in place of your original check. If the EFT cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

Checks may be sent:

By USPS Mail:	By courier:
U.S. Environmental Protection Agency Washington Finance Center FIFRA Service Fees P.O. Box 979074 St. Louis, MO 63197-9000	U.S. Bank Government Lockbox 979074 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63197 (314) 418-4990

Guidance on Small Business Waivers

1. Under what circumstances is a small business eligible for a fee waiver?

An applicant that meets the definition of a small business is eligible for a fifty percent (50%) waiver of the pesticide registration service fee. A small business means a corporation, partnership, or un-incorporated business that has 500 or fewer employees and during the 3-year period prior to the most recent maintenance fee billing cycle, has an average annual global gross revenue from pesticides that did not exceed $60 million (including any such revenue from all of its affiliates). In addition, a small business that has average annual global gross revenues from pesticides of less than $10 million (including any such revenue from all of its affiliates) over the past 3-year maintenance fee billing cycle at the time of the application is eligible for a 75% waiver of the pesticide registration service fee.

2. What is the previous "maintenance fee billing cycle" referred to in the statute?

The "maintenance fee billing cycle" is a yearly cycle commencing on January 15th. Therefore, the relevant time periods for measuring whether an applicant meets the definition of a small business are the applicant's three fiscal years preceding the January 15th of the year in which the application is received.

3. What are affiliates of an applicant for purposes of requesting a small business fee waiver?

Affiliates include direct and indirect subsidiary and parent entities of the applicant as well as entities that are controlled directly or indirectly by the owner(s) or any parent entity of the applicant. In addition, two unrelated entities are affiliates if they are both owned or controlled by the same entity or person. Specifically, business entities are affiliates of each other if, directly or indirectly, either entity controls or has the power to control the other entity, or a third entity controls or has the power to control both entities. Indicia of control include interlocking management or ownership, identify of interests among family members, shared facilities and equipment, and common use of employees. Accordingly, control is not limited to voting control over another entity.

4. What information should I include in my request for a fee waiver as a small business?

The request should be in writing and include the following information:

- The company name and company number assigned by OPP to the applicant, the official mailing address under FIFRA, the telephone number and e-mail or fax number of the contact person regarding the fee waiver or reduction request.
- A certification signed by a responsible officer that the documentation submitted to support the waiver or reduction request is true, complete, and correct.
- An ownership structure chart depicting the relationship of the applicant to subsidiaries and parent entities that are directly or indirectly controlled by the owner(s) or any parent entity of the applicant, if

appropriate. If the applicant does not have a parent entity, the percentage ownership interest of the direct and indirect
owner(s) or shareholders of the applicant should be disclosed. If the applicant does not have a parent entity, the percentage ownership interest of the direct and indirect owner(s) or shareholders of the applicant should be disclosed. If the applicant does have a parent company (or companies), the ownership of the ultimate parent entity should also be disclosed.

- A narrative or explanatory information, if appropriate, addressing
whether related entities are affiliates.
- A narrative or explanatory information, if appropriate, explaining
how the applicant differentiated its global gross receipts from pesticides from other revenue and how such revenue was calculated, both for the applicant and for any affiliates. The rationale should explain what types of revenues have been excluded.
- Appropriate supporting documentation demonstrating that the criteria for the waiver or reduction from the registration service fee are met.

Voluntary Small Business Waiver Form PDF (1 p, 29 kb, About PDF) (Embedded image moved to file: pic11855.jpg)-- A workgroup comprising representatives of registrant companies and trade associations designed a form for assisting pesticide registrants when they submit small business waiver requests under the Pesticide Registration Improvement Act. EPA staff provided input to the process. Use of the form is voluntary and information submitted using the forms will be accepted by the Agency. Other formats that meet the requirements of the statute will be acceptable to the Agency as well.

5. What information is required for certification for a fee waiver?
A certification should include:

1. information on business identification;
2. information regarding the number of employees of the applicant;
3. information regarding the ownership of the applicant and affiliated entities;
4. information regarding the global gross revenue from pesticides (of the applicant as well as any affiliates); and
5. a certification statement signed by a responsible officer that the information provided is true, complete, and correct.

Sincerely,

Teresa Downs
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670
www.epa.gov/pesticides

----- Message from <paygovadmin@mail.doc.twai.gov> on Tue, 7 Dec 2010 11:26:11 -0800 -----

To: "Carrie Daniels" <cdaniels@exponent.com>

Fee for Service

{8866054~

This package includes the following

- ○ New Registration
- ◉ Amendment

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

Receipt No. S- 886605

EPA File Symbol/Reg. No. 70127-6

Pin-Punch Date: 12/1/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted: B680

Amount Due: $ 4,631

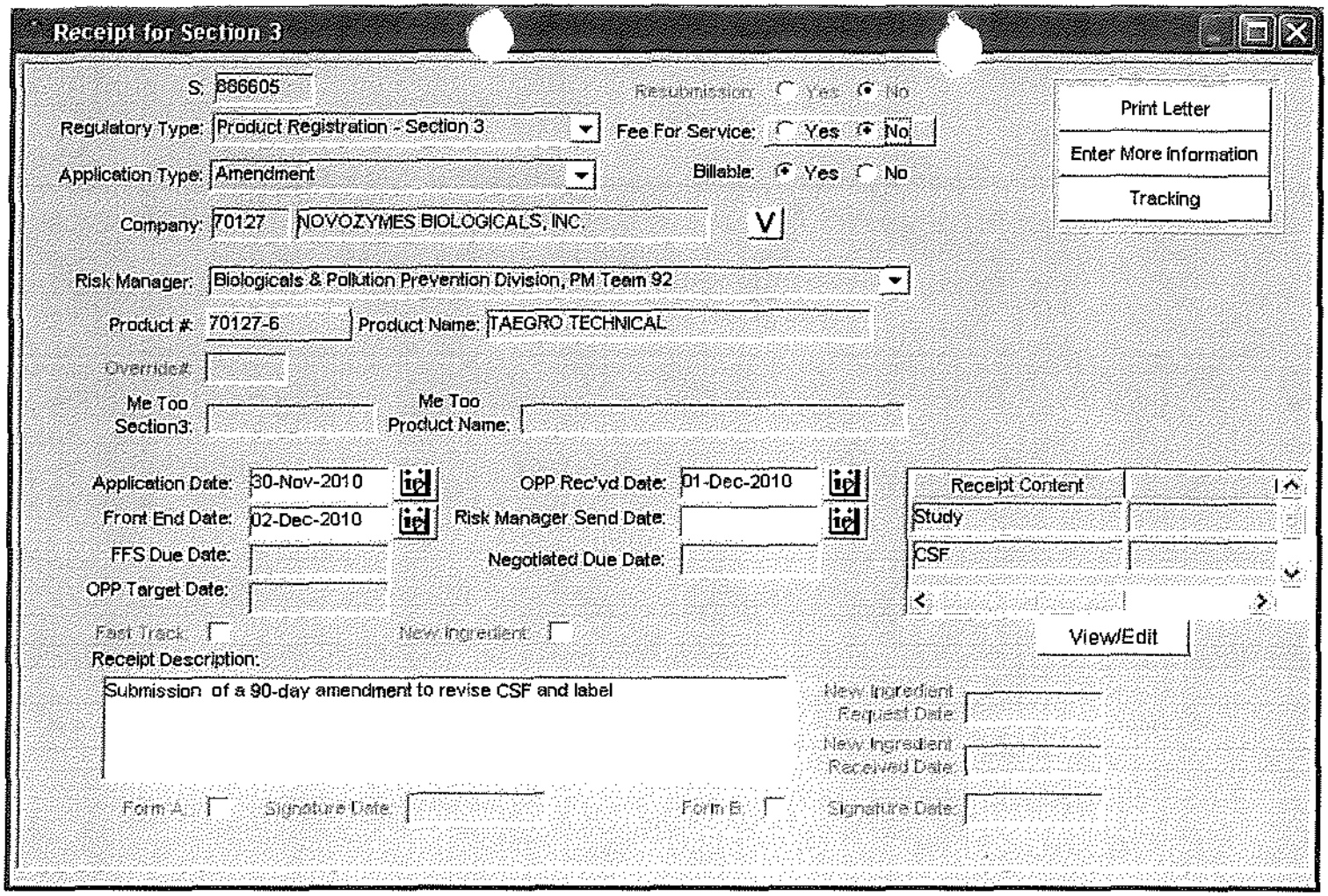
Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: S Reilly Date: 12/6/10

Remarks:

Co. thought this was non-PRIA
So did not submit payment
or request for waiver


Receipt for Section 3
S: 866605
Resubmission: Yes No
Print Letter
Enter More Information
Tracking
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 70127 NOVOZYMES BIOLOGICALS, INC.
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92
Product #: 70127-6
Product Name: TAEGRO TECHNICAL
Override #:
Me Too Section3:
Me Too Product Name:
Application Date: 30-Nov-2010
OPP Rec'vd Date: 01-Dec-2010
Front End Date: 02-Dec-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Submission of a 90-day amendment to revise CSF and label
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☒ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 70127-6
2. EPA Product Manager: Sheryl Reilly
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): Novozymes Biologicals, Inc. / Taegro Technical
   PM# BPPD
5. Name and Address of Applicant *(Include ZIP Code)*:
   Novozymes Biologicals, Inc.
   5400 Corporate Circle
   Salem, Virginia 24153
   ☐ *Check if this is a new address*
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

Section II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of a 90-day amendment to revise the CSF and Label for Taegro Technical and to submit a new Manufacturing Process.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) Plastic Bag
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions: ☐ On Can ☐ On Label/in accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Other _____ ☐ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Dean Thome
3. Title: Regulatory Affairs Manager, Novozymes Biologicals, Inc.
4. Typed Name: Dean Thome
5. Date: November 30, 2010

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

November 30, 2010

Dr. Sheryl Reilly, Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs, U.S. EPA (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Submission of a 90-day Amendment for a revised CSF, Label, and Manufacturing Process for Taegro Technical (EPA Registration No. 70127-6)

Dear Dr. Reilly:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, Virginia 24153, EPA Company Number 70127), Exponent is submitting an amended basic Confidential Statement of Formula (CSF) and product label, amended manufacturing process and a interim storage stability study for the product Taegro Technical, (EPA Registration No. 70127-6), containing the active ingredient *Bacillus subtilis* var. *amyloliquefacies* Strain FZB24. The following items are enclosed in support of this 90-day amendment:

- Transmittal Document;
- Application for Registration (EPA Form 8570-1);
- Revised Basic Confidential Statement of Formula (2 copies);
- Copy of Previously Approved Basic Confidential Statement of Formula;
- Data Matrix (Public and Private versions);
- Certification with Respect to Data Citation (EPA Form 8570-34);
- Five copies of the revised master label (one with changes highlighted);
- Amended manufacturing process; and
- Interim storage stability study.

The manufacturing process for Taegro Technical has been amended in three specific places and these amendments are described in detail in the enclosed "Amended Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)." Novozymes initiated this change in the manufacturing process because the new process is more efficient and allows for more material to be manufactured at one time. Novozymes has amended the fermentation medium, changed the drying process used in the production process, and amended the certified limits for the product.

These changes and their impact on Taegro Technical and the final end-use product, Taegro (EPA Registration No. 70127-5) are explained in the confidential section of the Amended Description of Beginning Materials and Manufacturing Process.

In addition to the revised manufacturing process, a new storage stability study is being conducted to demonstrate that the change in the manufacturing process has not affected the stability of the product. The study is on-going, however, Novozymes is submitting an interim report at this time, showing that there is no affect on the stability of Taegro Technical under the new manufacturing process.

The product label and CSF have been revised to reflect the changes made in the manufacturing process. The percent by weight of the active ingredient has been revised on the label and CSF, however, the nominal activity of the active ingredient, as expressed in colony forming units (CFUs)/gram, has not changed. Novozymes has slightly revised the upper and lower limits. This new Basic CSF dated November 19, 2010 will supersede the previous Basic CSF on file with the Agency.

Novozymes has conducted a new five-batch analysis, as required on the most recent stamped approved label for Taegro Technical, dated January 22, 2010. This 5-batch analysis study is being submitted under separate cover in response to the registration requirement, and the information in this study confirms that the revised process meets the specifications on the new CSF submitted here.

Should you have any questions regarding this submission, please contact me via telephone at 202-772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes Biologicals, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153

CONTACT PERSON (Return to)

Carrie Daniels
Exponent, Inc.
1150 Connecticut Ave., N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Submission of a 90-day amendment for a revised CSF, Label, Manufacturing Process, and Stability Study for Taegro Technical (EPA Registration No 70127-6).

SUBMITTAL DATE:

November 30, 2010

Volume	Study Title	MRID No.
1	Administrative Package	
2	Amended Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)	**48311901**
3	Interim Storage Stability Study for Taegro Technical (70127-6)	**48311902**

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0154

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Novozymes Biologicals, Inc. 5400 Corporate Circle, Salem, VA, 306-657-8238	EPA Registration Number/File Symbol 70127-6
Active Ingredient(s) and/or representative test compound(s) Bacillus subtilis var.amyloliquefaciens Strain FZB24	Date 11/30/10
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food use and non-food use	Product Name Taegro Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Dean Thome	11/30/2010	Dean Thome, Regulatory Affairs Manager

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 1 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100, 885.1200	Description of Beginning Materials and Manufacturing Process for Taegro Technical (70127-6)	New Submission	Novozymes Biologicals, Inc.	OWN	
885.1400	5 Batch Analysis for Taegro Technical (70127-6)	New Submission	Novozymes Biologicals, Inc.	OWN	
830.6317	Stability Study for Taegro Technical (70127-6)	New Submission	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1500,	Product Identification and Disclosure of Ingredients Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG.	44758101	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1200	Description of Beginning and Manufacturing Process Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG	44758102	Novozymes Biologicals, Inc.	OWN	
885.1300	Discussion of the Formation of Impurities Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG	44758103	Novozymes Biologicals, Inc.	OWN	
885.1400	Lot Analysis of Bacillus subtilis var. amyloliquefaciens Strain FZB24: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN23	44758104	Novozymes Biologicals, Inc.	OWN	
885.1500	Certification of Ingredient Limits: TAE-022 Technical, TAE-WDG	44758105	Novozymes Biologicals, Inc.	OWN	
885.1100, 885.1200, 885.1300, 885.1400, 885.1500	Responses to Question Raised Regarding MRID Numbers 44758102, 44758103, 44758104, and 44758105 TAE-022 Technical and WDG Bacillus subtilis var. amyloliquefaciens Strain FZB24	44976001			
830.6302, 830.6303, 830.6304, 830.7300, 830.7000	Determination of the Color, Physical State, Odor, pH, and Density of Bacillus subtilis var. amyloliquefaciens: TAE-022 Technical, TAE-WDG: Lab Project Number: 495C-101	44758106	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 11/30/2010

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 2 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100, 885.1200, 885.1400	Response to Questions Raised Regarding MRID Numbers 4475102 and 4475104 TAE-022 Technical and WDG Bacillus subtilis var. amyloliquefaciens Strain FZB24.	44986501	Novozymes Biologicals, Inc.	OWN	
830.6302, 830.6303, 830.6304, 830.7300, 830.7000	Determination of the Color, Physical State, Odor, pH, and Density of Bacillus subtilis var. amyloliquefaciens End-Use Product: TAE-022 Technical, TAE-WDG: Lab Project Number: 495C-103.	44758107	Novozymes Biologicals, Inc.	OWN	
885.3050 (870.1100)	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, Following Acute Oral Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN2	44758108	Novozymes Biologicals, Inc.	OWN	
885.3050 (870.1100)	Acute Toxicity/Limit Testing of Bacillus subtilis var. amyloliquefaciens, Strain FZB24, WDG End Use Product, Following Acute Oral Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN8.	44758109	Novozymes Biologicals, Inc.	OWN	
885.3100 (870.1200)	Acute Dermal Toxicity/Pathology Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN5	44758110	Novozymes Biologicals, Inc.	OWN	
885.3100 (870.1200)	Acute Dermal Toxicity/Pathology Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, WDG End Use Product in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN10	44758111	Novozymes Biologicals, Inc.	OWN	
885.3150 (870.1300)	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, Acute Intratracheal Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN3.	44758112	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 11/30/2010

EPA Form 8570-35 [illegible]-Electronic and Paper Versions Available Submit only Paper version.

Agency Internal Use Copy
Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 3 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3200	Toxicity/Pathogenicity Testing of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, Following Acute Intravenous Challenge in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN4.	44758113	Novozymes Biologicals, Inc.	OWN	
870.2400	Primary Eye Irritation Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN6	44758114	Novozymes Biologicals, Inc.	OWN	
870.2400	Primary Eye Irritation Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, WDG End Use Product in Rabbits: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN1.	44758115	Novozymes Biologicals, Inc.	OWN	
885.3400	Hypersensitivity Incidents Report Bacillus subtilis var. amyloliquifaciens Strain FZB24: TAE-022 Technical, TAE-WDG.	44758116	Novozymes Biologicals, Inc.	OWN	
885.3400	Sensitivity of Detection of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, for Toxicity/Pathogenicity Testing in Rats: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743SN1.	44758120	Novozymes Biologicals, Inc.		
870.2600	Dermal Sensitization Study of Bacillus subtilis var. amyloliquifaciens, Strain FZB24 in Guinea Pigs Using the Buehler Method: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN7	44758117	Novozymes Biologicals, Inc.	OWN	
NA	Potential Health Effects of Bacillus subtilis var. amyloliquifaciens Strain FZB24 A Review of Literature: TAE-022 Technical, TAE-WDG.	44758118	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 11/30/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 4 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Growth Parameters of Bacillus subtilis var. amyloliquifaciens, Strain FZB24, at Various Temperatures: TAE-022 Technical, TAE-WDG: Lab Project Number: L08743 SN25	44758119	Novozymes Biologicals, Inc.	OWN	
885.4050	Bacillus subtilis var. amyloliquifaciens: An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite: TAE-022 Technical, TAE-WDG: Lab Project Number: 495-101.	44758121	Novozymes Biologicals, Inc.	OWN	
885.4200	Bacillus subtilis var. amyloliquifaciens: A Five-Concentration Toxicity and Pathogenicity Test with the Rainbow Trout (Oncorhynchus mykiss): TAE-022 Technical, TAE-WDG: Final Report: Lab Project Number: 495A-102.	44758123	Novozymes Biologicals, Inc.	OWN	
885.4240	Bacillus subtilis var. amyloliquifaciens: A 21-Day Life-Cycle Toxicity and Pathogenicity Test with the Cladoceran (Daphnia magna): TAE-022 Technical, TAE-WDG: Final Report: Lab Project Number: 495A-101.	44758122	Novozymes Biologicals, Inc.	OWN	
885.4300	Algae Growth Inhibition Test--Test Article Bacillus subtilis Strain FZB24: TAE-022 Technical, TAE-WDG: Lab Project Number: 83-00-0551-00-93	44758127	Novozymes Biologicals, Inc.	OWN	
885.4380	Evaluation of the Dietary Effect(s) of Bacillus subtilis var. amyloliquifaciens on Honey Bee Larvae (Apis mellifera L.): TAE-022 Technical, TAE-WDG: Lab Project Number: CAR 167-98.	44758124	Novozymes Biologicals, Inc.	OWN	
885.4380	Evaluation of the Dietary Effect(s) of Bacillus subtilis var. amyloliquifaciens on Adult Honey Bees (Apis mellifera L.): TAE-022 Technical, TAE-WDG: Lab Project Number: CAR 169-98.	44758125	Novozymes Biologicals, Inc.	OWN	
NA	Bacillus subtilis var. amyloliquifaciens Strain FZB 24: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate: TAE-022 Technical, TAE-WDG: Lab Project Number: 495-102.	44758126	Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thonte, Regulatory Affairs Manager		Date 11/30/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 1 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature			Name and Title Dean Thome, Regulatory Affairs Manager		Date 11/30/2010

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Only

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director; OPPE Information Management Division (2137) U S Environmental Protection Agency, 401 M Street, S W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 30, 2010	EPA Reg No./File Symbol 70127-6	Page 2 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153	Product Taegro Technical	

Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	

Signature	Name and Title	Date
Dean Thome	Dean Thome, Regulatory Affairs Manager	11/30/2010

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version

Agency Internal Use Copy
Form Approved OMB No. 2070-0060

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available Submit only Paper version.

Agency Internal Use Copy
Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: DPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 30, 2010	EPA Reg No./File Symbol 70127-6	Page 3 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153	Product Taegro Technical	

Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.		
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	

Signature	Name and Title	Date
Dean Thome	Dean Thome, Regulatory Affairs Manager	11/30/2010

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 30, 2010			EPA Reg No./File Symbol 70127-6		Page 4 of 4
Applicant's/Registrant's Name & Address Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem VA 24153			Product Taegro Technical		
Ingredient *Bacillus subtilis var.amyloliquefaciens Strain FZB24*					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
			Novozymes Biologicals, Inc.	OWN	
Signature Dean Thome			Name and Title Dean Thome Regulatory Affairs Manager		Date 11/30/2010

Memorandum

Date: 12 / 08 / 10

To: PM:92, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☑ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

MATERIAL TO BE ADDED TO JACKET

REG #: 70127-6

Description: Fast track label amendment / Registration notice correction

if applicable, check all that are attached:		
☒	new stamped accepted label	Send to CSC
☐	new CSF	
☐	notification	
☐	other:	

Instructions:
Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Jeannine Kausch Date: 1/22/2010

Phone: (703) 347-8920 Division: BPPD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:	Date of Issuance:
70127–6	JAN 2 2 2010
Term of Issuance:	Unconditional
Name of Pesticide Product:	Taegro Technical

NOTICE OF PESTICIDE:

__X__ Registration
_____ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Novozymes Biologicals, Incorporated
5400 Corporate Circle
Salem, VA 24153

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If the EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit a five-batch analysis from batches produced at the new manufacturing facility in Salem, Virginia by February 15, 2011 (in accordance with OPPTS Harmonized Guideline 885.1400).

2. Submit two (2) copies of the final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of a final printed label.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:	Date:
W. Michael McDavit, Associate Director Biopesticides and Pollution Prevention Division	JAN 2 2 2010

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	KAUSCH							
DATE	01/22/2010	1/22/10						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY
142

U.S. Government Printing Office: 2005 206-889 (mac)

UNIT STATES ENVIRONMENTAL PROTECTIO GENCY

Mr. Thomas Schreier
Regulatory Affairs Manager
Novozymes Biologicals, Incorporated
5400 Corporate Circle
Salem, VA 24153

JAN 2 2 2010

Re: Novozymes Biologicals, Incorporated; Taegro Technical
EPA Registration No. 70127–6
Registration Notice Correction Request / Minor Label ("Fast Track") Amendment
Submissions dated 01/29/2008 and 08/03/2009
Decisions #389764 and #418264

Dear Mr. Schreier:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

1) Correction of minor formatting and typographical errors.
2) Conversion of the product brand name from "TAE Technical" to "Taegro Technical."
3) Removal of the Spanish signal word ("AVISO") and Spanish statement ("Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle."), along with its associated English translation ("If you do not understand the label, find someone to explain it to you in detail."), as this product is not subject to the Worker Protection Standard.
4) Addition of a referral statement should the Precautionary Statements occur on the container in a location other than the front panel.
5) Adjustment of "Net Contents:" to "Net Weight:" given that the product is a dry formulation.
6) Modification of the EPA Establishment Number from "70127-VA-006" to "70127-VA-010."
7) Modification of the First Aid and Hazards to Humans and Domestic Animals statements so that they coincide with the toxicity categories obtained from the supporting data.
8) Addition of manufacturing-use product specific statements to the Directions for Use.
9) Revision of the Storage and Disposal statements, in accordance with Pesticide Registration (PR) Notices 2007-4 and 83-3, to match the product's specified container type.

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	KAUSCH	[signature]						
DATE	01/22/2010	1/22/10						

EPA Form 1320–1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

* U.S. Government Printing Office: 2005 206–809 (mac)

In addition to the label amendment, you also requested a revised registration notice (J. Messina to S. Reilly; letter dated January 29, 2008) due to a mistake made on the Agency's part, which resulted in the incorrect application of particular conditions to this product in the notice of pesticide registration dated February 12, 2007. This processing error has been acknowledged and, accordingly, the Agency has corrected and is reissuing the registration notice for Taegro Technical.

The changes referred to on the previous page, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you:

1) Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of this condition. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

The corrected registration notice and a stamped copy of the label are enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (3):
- Unconditional Registration Notice
- A-79 Enclosure
- Acceptable Label

TAEGRO Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	73.3%
OTHER INGREDIENTS	26.7%
Total	100.0%

*Contains 5.0×10^{11} Colony Forming Units [(CFU)]/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]
[This statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally from 100 to 500 lb.]

Novozymes Biologicals, Inc.
5400 Corporate Circle, Salem, VA 24153
1-800-342-6173
www.novozymes.com

Made in U.S.A.
EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-010

Not for sale or use after: [Date to be inserted]

ACCEPTED

JAN 2 2 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70127-6

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled, or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE

TAEGRO consists of living microbes. Do not freeze or expose to temperatures above 80° F. Close opened containers tightly. Store in a cool, dry place and use within one year.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill container.

Completely empty bag into formulation equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Note to reviewer: The "Not for sale or use after (date)" is to serve as the batch code.]
[Note to reviewer: This product is sold in large plastic bags contained in cardboard frames.]

ROUTING AND TRANSMITTAL SLIP Date: 01/22/2010

TO: *(Name, office symbol, room number, building, Agency)*		
Sheryl Reilly	SRT	1/22/10

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify	X	Concurrence

REMARKS

Fast track label amendment and registration notice correction for Taegro Technical (EPA Reg. No. 70127-6)

**Please see the letter for a complete list of revisions made to this label during the course of the latest review.

**Checklists associated with this action are also enclosed and can be found on the left-hand side of the folder.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: *(Name, org. symbol, Agency/Post)*	Room No.--Bldg.
	S-8931
Jeannine Kausch	Phone No.
	(703) 347-8920

Label Review

File Symbol: 70127-6 **Date:** 08/03/2009 **Reviewer:** J. KAUSCH

[Site/Use]	[Res /Ag /Both] ↳ MUP	[Food /Non-Food /Both] ↳ MUP
[Tox Categories:]	[AcOral: 3 /AcDerm: 3 /AcInhl: 3 /EyeIrr: 2 /SkinIrr: 2 DermSens: –]	

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide	---	---	---		**Ch 6**
Product Name	X				Pg 12-3
Compny Name and Info	X				Pg 15-1
Identification Numbers	X				**Ch 14**
Net Contents		X		Need clarification on certain items	**Ch 17**
Ingredients Statement	X				**Ch 5**
Label Claims			X		Pgs 4-5, **5-7** 11-10 & **Ch 12**
Alternate Formula			X		5-12

ALL ISSUES HAVE BEEN ADDRESSED AS OF 01/21/2010. -JRK

Precautionary Statements

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC	X				3-1 & 9 7-3 & 4
Signal Word		X		Spanish translation not necessary	**Ch 3 Ch 7 Ch 10**
General Heading >PRECAUTIONARY STATEMENTS=	X				Ch 7
First Aid (PRN 20001-1)		X		Rearrange routes of exposure	**Ch 3 & 7**
Hazards to Humans and Domestic Animals		X		PPE-specific	Ch 3, 7-3
PPE (WPS) Engineering Controls			X		Ch 7, Pg 7-12 Pgs 10-4, 15
User Safety Requirements			X		Ch 10
User Safety Recommendations			X		Ch 10
Environmental Hazards	X				Ch 8
Physical and Chemical Hazards	X				Pg 3-4 Ch 9

Directions for USE (FIFRA Text, WPS plus Storage and Disposal					
Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
Header >Directions for Use=	X				10-16
Violation of Federal Law text		X		Minor adjustment	10-26, 11-7
WPS Text (PPE)			X		Ch 10, 7-1 7-11
Non-WPS Text			X		7-12, **Ch 10**
Storage and Disposal		X		PR Notice 2007-4	11-16, **Ch 13**

Directions for Use (General Instructions and Information)					
Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
General Instructions and Sub-Header		X		More specific	
Chemigation / Prohibition			X		PRN
REI			X		Pg 10-20

Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
General Info. (non-site specific info. on uses, pests, mixing, and loading, tank mixing, etc.)			X		
General Precautions and Restrictions			X		
Directions for Use					
Directions for Application			X		
Warranty Information					
Consistency with label instructions	X				12-6
Not false or misleading	X				

"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, ato the extent allowable by state lawe, or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or injury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."

BPPD Label Amendment Checkli
Fast Track ☑

EPA Reg. No.: 70127-6 **RAL:** J. Kausch **Application Date: 08/03/2009**

#	Check list Item	Yes	No
1.	**Application Form** (EPA Form 8570-1) - signed & complete, including package type? **IF NO, STOP!** Call applicant and have them correct application and resubmit.	■	
2.	**Final printed labeling** received for previous action? **IF NO, STOP!** E-mail applicant and request final printed labeling (FPL). *These have been requested and registrant confirmed he will provide them (see email dated 01/22/2010).		■
3.	**Data and Data Matrix** present. (EPA Form 8570-35) NA ☑ If Fast Track, check to see if original registration supported by data, formulators exemption, etc.		
a.	Using Selective Method? [**IF NO, SKIP to item 4 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.**]		
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.		
c.	Adequate product specific data?		
d.	Registered source used for active ingredient? **IF YES, SKIP to ITEM 4.** (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) **If NO or if use not supported by registered source**, generic data is necessary.		
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
4.	**Certification with Respect to Citation of Data** present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA ☑		
a.	Did applicant check a Method of Support?		
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		
c.	Is the form signed and dated?		
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources?		
	IF YES, is the required authorization letter included in application? NA ☐		
5.	**Label(s) Review** **Date of Label Review:** 08/03/2009		
a.	Label(s) in conformance with current *Label Review Manual* and appropriate REDS.	■	
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.	■	
c.	Nominal concentration of active ingredient shown in ingredients statement.	■	
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).	■	
e.	Storage and disposal instructions agree with container types listed on application form. *changed to bags	■	
f.	Unique Product Name for Same Company (Check OPPIN).	■	
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? **If YES**, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		■
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		■
	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer? (see NOP/OMRI checklist)		
i.	Labeling is acceptable. Corrections or changes are NOT necessary.	■	
j.	Comments:		

RE: Label Comments/Revisions for Taegro Technical (#70127-6)
Jeannine Kausch to: TASC (Tom Schreier) 01/22/2010 10:05 AM

Hi Tom,

You can address your cover letter to me but be sure to send the package to one of the locations below, depending on whether it is sent via mail or by courier:

1) Mail

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

2) Courier

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Also, in your cover letter, please make a note that you are submitting the final printed labels as requested by the Agency in the original January 20, 2000 registration notice.

Thanks,

Jeannine

"TASC (Tom Schreier)" Hi Jeannine, I will send the labels in. Who... 01/22/2010 08:19:15 AM

From: "TASC (Tom Schreier)" <tasc@novozymes.com>
To: Jeannine Kausch/DC/USEPA/US@EPA
Date: 01/22/2010 08:19 AM
Subject: RE: Label Comments/Revisions for Taegro Technical (#70127-6)

Hi Jeannine,
I will send the labels in. Who should I address them to?

Tom

Best Regards
Tom Schreier
Regulatory Affairs

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Thursday, January 21, 2010 6:06 PM
To: TASC (Tom Schreier)
Subject: Fw: Label Comments/Revisions for Taegro Technical (#70127-6)

Hi Tom,

One last thing I noted as missing that usually goes along with our checklist for final processing of label amendments...Would you mind submitting (to the document processing desk) 2 copies of the final printed labeling that you have been using on your Taegro Technical containers for the past several years? The original registration notice from January 2000 asked for copies, but these were never submitted to the Agency as requested.

Let me know if you have any questions about this. I will still proceed with the label amendment as mentioned below, but I wanted to ensure that I close the loop completely for this product.

Thanks,

Jeannine
----- Forwarded by Jeannine Kausch/DC/USEPA/US on 01/21/2010 05:03 PM -----

From: Jeannine Kausch/DC/USEPA/US

To: "TASC (Tom Schreier)" <tasc@novozymes.com>

Date: 01/21/2010 04:12 PM

Subject: RE: Label Comments/Revisions for Taegro Technical (#70127-6)

Hi Tom,

I've looked over the label and everything that you've updated appears to be fine. I will probably get around to drafting an acceptance letter tomorrow and pass it up to management shortly thereafter. Look for another update sometime next week.

Thanks again for the prompt response,

Jeannine

From: "TASC (Tom Schreier)" <tasc@novozymes.com>

To: Jeannine Kausch/DC/USEPA/US@EPA

Date: 01/21/2010 11:29 AM

Subject: RE: Label Comments/Revisions for Taegro Technical (#70127-6)

HI Jeannine,
Please find attached a corrected label in word format. There have been some changes to our procedures that I have incorporated into this label. Our product packaging has changed from reusable plastic to plastic bags in a cardboard frame on pallets. I believe that I used the correct statements to support this, but please check. I have also changed the establishment number. All other changes are as you described.

Thank you for all of your help.

Tom

Best Regards
Tom Schreier
Regulatory Affairs

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [
mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Monday, January 18, 2010 1:50 PM
To: TASC (Tom Schreier)
Subject: Fw: Label Comments/Revisions for Taegro Technical (#70127-6)

Fw: Label Comments/Revisions for Taegro Technical (#70127-6)

Jeannine Kausch to: TASC (Tom Schreier) 01/18/20 t0 01:50 PM

Hi Tom,

I apologize for hassling you, but I have not heard back from you with regard to the corrections for the Taegro Technical (#70127-6) label. As this particular action was assigned a "90-day" amendment code back in August 2009, it will be overdue by nearly 3 months at the beginning of February. Unfortunately, if I do not get a response back from you by the end of this week (i.e., January 25th), I will have to initiate a 75-day letter and provide you a list of corrections formally via regular mail.

Thanks,

Jeannine

----- Forwarded by Jeannine Kausch/DC/USEPA/US on 01/18/2010 01:43 PM -----

From:	Jeannine Kausch/DC/USEPA/US
To:	TASC (Tom Schreier) <tasc@novozymes.com>
Date:	11/03/2009 12: t8 PM
Subject:	Fw: Label Comments/Revisions for Taegro Technical (#70127-6)

Hi Tom,

Just checking in with you in regards to the label comments that I provided for your Taegro Technical product (#70127-6) back in August. Please let me know if you have any questions about the suggested revisions.

Thanks for your attention to this matter.

Regards,

Jeannine

----- Forwarded by Jeannine Kausch/DC/USEPA/US on 11/03/2009 12:14 PM -----

From:	Jeannine Kausch/DC/USEPA/US
To:	TASC (Tom Schreier) <tasc@novozymes.com>
Date:	08/03/2009 11:24 AM
Subject:	Label Comments/Revisions for Taegro Technical (#70127-6)

Hi Tom,

As I mentioned during our phone conversation last week, I am attaching my comments for the Taegro Technical label (#70127-6). Based on what I can find in the documentation that was provided to me, it looks like you sent in the request for the label amendment back in November 2008!! My sincere apologies that this is the first time someone from the Agency is getting back to you with regard to this submission. However, now that I've gone through it, I don't believe it will take an extraordinary amount of time to revise the label and get a proper response back to you.

Let me know if you have any questions about my label comments. You can submit your updates to me via email.

Thanks,

Jeannine

70127-00006.20081121v001.Taegro Technical_comments.pdf

TAEGRO Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	73.3%
OTHER INGREDIENTS	26.7%
Total	100.0%

*Contains 5.0 x 10^{11} Colony Forming Units [(CFU)]/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net contents: _____ [Value to be inserted, generally from 15 to 500 gal]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-800-342-6173•
www.novozymes.com/roots

Made in U.S.A.
EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-006

Not for sale or use after: [Date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - Causes substantial but temporary eye irritation. Avoid contact with eyes. Wear protective eyewear such as goggles, face shield or shielded safety glasses. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Summary of Comments on Microsoft Word - TAEGRO-Technical.doc

Page: 1

Sequence number: 1
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 6:04:57 AM -04'00'

The Spanish translation for the signal word, as well as the statement about asking for help, are not required for the manufacturing use product because it is not covered under the Worker Protection Standard. However, if you believe this translation will be helpful for a majority of the product's users, then you may leave this as is.

Sequence number: 2
Author: jkausch
Subject: Note
Date: 8/3/2009 9:09:45 AM -04'00'

Under the signal word, please place a statement referring the user to another part of the container for the precautionary statements. For example:

See additional precautionary statements on the [side][back] panel.

Sequence number: 3
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 9:13:45 AM -04'00'

Is this an accurate statement? The EPA Form 8570-1 states that this product will be packaged in 250 or 500 gallon plastic containers. Please update as necessary. Also, the weight or contents of the containers should fit the physical state of the formulation (e.g., if this is a solid, it might be packaged in 200 pound containers).

Sequence number: 4
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:52:17 AM -04'00'

If this technical product is a solid, please change to "Net Weight:". If this technical product is a liquid, you may leave this as "Net Contents:".

**LRM Chapter 17, Section III

Sequence number: 5
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 8:16:54 AM -04'00'

Based on the toxicological profile for the technical (dermal tox - III, dermal irritation - II, oral tox - III, inhalation - III, eye irritation - II, and sensitization - not a sensitizer), this section should be the following:

WARNING - Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled, or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

***LRM Chapter 7, Section III(D)

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

Page: 2

Sequence number: 1
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:35:18 AM -04'00'

Restructure this First Aid box so that the routes of exposure of most concern are listed at the top of the box and those of least concern are listed near the bottom. In this case, the order from top to bottom should be a) eye statements, b) skin statements, c) inhalation statements, and d) oral statements.

**LRM Chapter 7, Section III(F)(3)

Sequence number: 2
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:53:28 AM -04'00'

Please remove the capitalization from "poison control center."

Sequence number: 3
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:55:18 AM -04'00'

Please insert a 3rd bullet beneath these two bullets:

Call a poison control center or doctor for further treatment advice.

**LRM Chapter 7, Section III(F), Table 9

Sequence number: 4
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:30:33 AM -04'00'

Please insert a comma after "doctor."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into pesticide products. The user is responsible for registering products made from TAEGRO Technical with the appropriate regulatory authorities.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

TAEGRO consists of living microbes. Do not freeze or expose to temperatures above 80° F. Close opened containers tightly. Store in a cool, dry place and use within one year.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents from this container into formulation equipment. Fill the container about 10% full with water. Agitate vigorously for 2 minutes. Pour rinsate into formulation equipment. Repeat this rinsing procedure two more times.

Page: 3

Sequence number: 1
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:23:56 AM -04'00'

Please capitalize.

Sequence number: 2
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 9:10:48 AM -04'00'

These statements could be a little more specific. Perhaps, try something like the following:

For formulation into a [type of pesticide] for use in/on [list use patterns and sites[. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

**LRM Chapter 11, Section V(A)

Sequence number: 3
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:02:19 AM -04'00'

Please change to "and."

**LRM Chapter 13, Section III

Sequence number: 4
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:03:43 AM -04'00'

I am going to ask that you go back to the older "Pesticide Disposal" statement for this product only. Because this is a manufacturing-use product and there really are no instructions for applying the product, please use the following statement in lieu of the current statements:

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**LRM Chapter 13, Section V(C)(1)

Sequence number: 5
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:02:08 AM -04'00'

Please change to "CONTAINER HANDLING."

**LRM Chapter 13, Section V(C)(2)

Sequence number: 6
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:12:32 AM -04'00'

I am fine with these directions (as they are mostly in accordance with the standard instructions mentioned in 40 CFR 156.156(b)(2)(iii)); however, please just check that the addition of water to whatever is being formulated will not cause any issues with the resulting product's composition, efficacy, etc.

---

[1]Note to reviewer: The "Not for sale or use after (date)" is to serve as the batch code.]
[Note to reviewer: This product is sold in large plastic totes.]

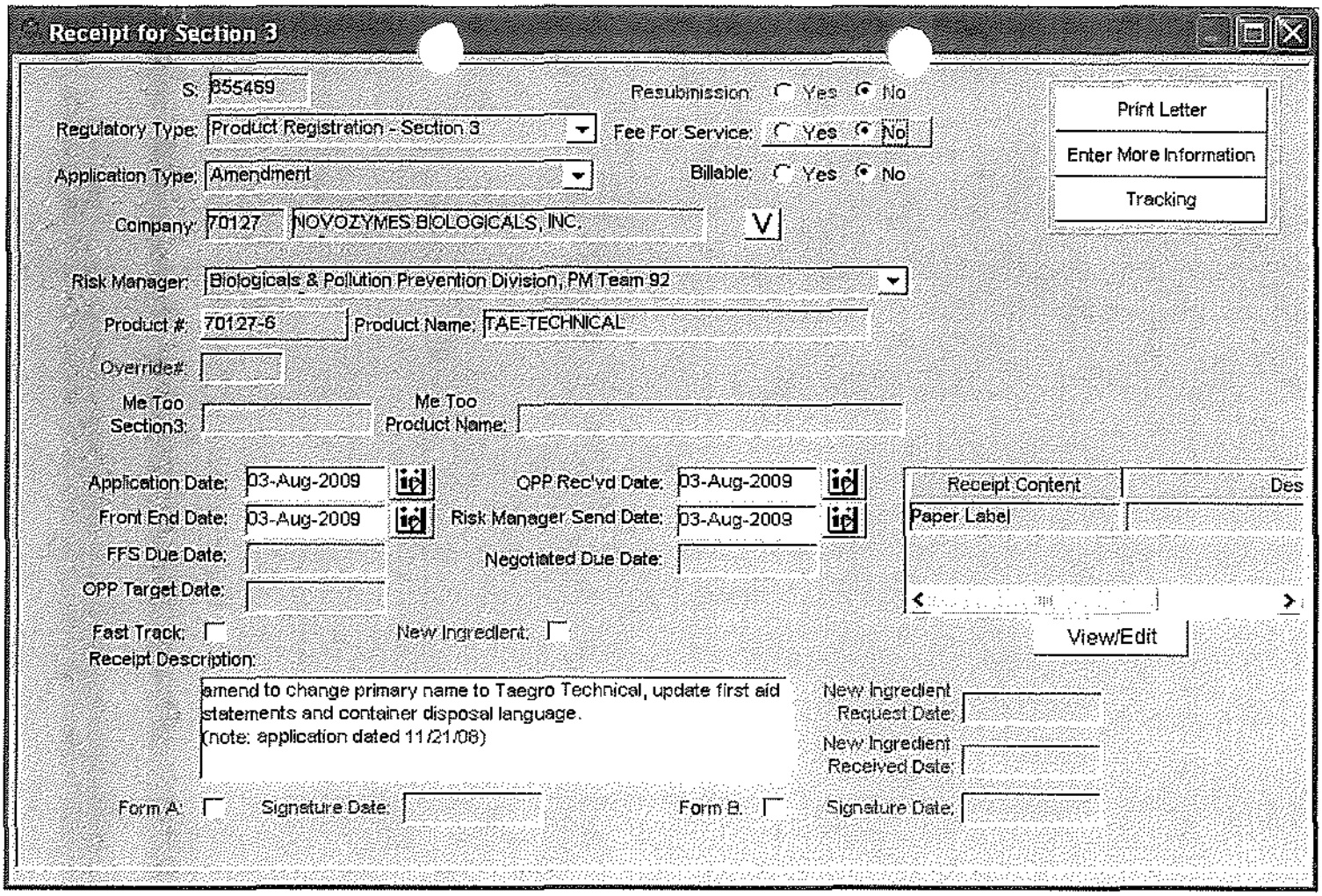
File:
70127-00006.20081121v001.Taegro Technical.pdf

Page: 4

Sequence number: 1
Author: jkausch
Subject: Comment on Text
Date: 8/3/2009 7:07:36 AM -04'00'

"T Although the "not for sale or use after (date)" may be needed on this label, the batch code is not required under the regulations because you have noted that this product is packaged in a refillable container. Batch codes only apply to non-refillable containers. You may remove this clarifying statement.

**40 CFR 156.140(a)(4)



AIO-Jeannine
AUG 11 2009

novozymes®
Rethink Tomorrow

November 21, 2008

Taegro Technical
EPA Registration No. 70127-6
Name Change and Label Revision

Shanaz Bacchus
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7504P)
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Bacchus,

In response to your e-mail dated 19 November 2008, Novozymes Biologicals is pleased to submit a request for a change of name for the product TAE Technical, EPA Registration Number 70127-6. To support this action Novozymes is submitting a revised label that includes this change.

Product Name:

- Old Name: TAE Technical
- New Name: Taegro Technical

Please find enclosed the following documents:

- One copy of EPA form 8570-1, Application for Pesticide.
- Three copies of the revised label.

If you have any questions or need any assistance in this matter, please contact me in Roanoke VA at (540) 302-1186 or by e-mail at: tasc@novozymes.com.

Sincerely,

Thomas Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
Phone: 800 859 2972 • 540 389 9361 • Fax: 540 389 2688
www.novozymes.com/microorganisms

Please read instructions on reverse before ...pleting form. Form Appro... OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Shanaz Bacchus	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Novozymes Biologicals / TAE Technical / Taegro Technical		

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals Inc.
5400 Corporate Circle
Salem, VA 24153

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Request that the name TAE Technical be changed to Taegro Technical.
2. Revised labeling to support this name change, updated first aid statements, and container disposal is also being submitted.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [x] Container	250 or 500 gal.	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schreier tasc@novozymes.com	Regulatory Affairs Mgr.	(540) 302-1186

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Thomas Schreier	Regulatory Affairs Manager
4. Typed Name	**5. Date**
Thomas Schreier	11/21/2008

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

TAEGRO Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24*	73.3%
OTHER INGREDIENTS	26.7%
Total	100.0%

*Contains 5.0×10^{11} Colony Forming Units [(CFU)]/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net contents: _____ [Value to be inserted, generally from 15 to 500 gal]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-800-342-6173•
www.novozymes.com/roots

Made in U.S.A.
EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-006

Not for sale or use after: [Date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - Causes substantial but temporary eye irritation. Avoid contact with eyes. Wear protective eyewear such as goggles, face shield or shielded safety glasses. Harmful if absorbed through skin, inhaled or swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into pesticide products. The user is responsible for registering products made from TAEGRO Technical with the appropriate regulatory authorities.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

TAEGRO consists of living microbes. Do not freeze or expose to temperatures above 80° F. Close opened containers tightly. Store in a cool, dry place and use within one year.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents from this container into formulation equipment. Fill the container about 10% full with water. Agitate vigorously for 2 minutes. Pour rinsate into formulation equipment. Repeat this rinsing procedure two more times.

[Note to reviewer: The "Not for sale or use after (date)" is to serve as the batch code.]
[Note to reviewer: This product is sold in large plastic totes.]

File:
70127-00006.20081121v001.Taegro Technical.pdf

Shanaz
Bacchus/DC/USEPA/US
11/19/2008 12:48 PM

To "TASC (Tom Schreier)" <tasc@novozymes.com>
cc
bcc
Subject 70127-6 and 70127-7

TAE-GRO Technical

These are two pesticides with similar names but different active ingredients:
70127-6 - **TAE-Technical** - *Bacillus subtilis var amyloliquefaciens* Strain FZB24
70127-7 - **TAE-001 Technical Bioinsecticide** - *Metarrhizium anisopliae* F52

70127-6 *(B. subtilis var amyloliquefaciens)* and **70127-7 (*Metarrhizium anisopliae*) products.**
I have a request from Novozymes for BPPD to correct a registration notice for a pesticide (EPA Reg. No.70127-6) which contains *Bacillus subtilis var amyloliquefaciens* Strain FZB24 as the active ingredient. It was given unconditional registration under FIFRA Section (3(C)(5) on **01/20/2000.** It is called **TAE-Technical** on the transfer letter. BPPD's revised Notice of registration (02/12/2007) to your company **with the EPA Reg. No. 70127-6 was issued with the name TAE-Technical for the B. subtilis product, while incorrectly containing the conditions of registration for the *Metarrhizium* F52 technical - called TAE-001 Technical Bioinsecticide**, (EPA Reg.No. 70127-7)

What may have contributed to the confusion is the similarity in the two names. While we are amending the labels for Metarrhizium products, would you consider changing the name for the *Metarrhizium* technical? Also, have you submitted an updated label and CSF for 70127-6, the *B. subtilis* product?

As discussed at our last meeting, as part of the *Metarrhizium* amendments, I am preparing new registration notices updating your case for *Metarrhizium* and working with Susanne Cerrelli, who has been the RAL on the *B. subtilis* case to resolve the issues about the B. subtilis pesticide discussed above.

Please call to discuss what potential exists for changing the names of these technicals to prevent future confusion.
Thanks.

Sincerely,
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511P)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

- update first tech container
- 2007-1026
6012

Ticks

Jan 2000

II dermal + eye 2

PChem

website ⟷

Mr. Schrier
540-372-1186

Shanaz
Bacchus/DC/USEPA/US
10/15/2008 04:16 PM

To Sheryl Reilly/DC/USEPA/US@EPA
cc Susanne Cerrelli/DC/USEPA/US@EPA, Ibrahim Barsoum/DC/USEPA/US@EPA
bcc
Subject 70127-6 (B. subtilis amylo) - 70127-7 and 70127-9 (Metarrhizium) products- comments please

Sheryl et al.:
Please look at this email I would like to send to Tom Schrier of Novozymes and provide input. Sheryl, especially look at the end of the email to see if the modified process with QA/QC data will be a PRIA action and what will be the cost and time frame for review.
Thanks,
shawn

.....

Correct reg notice

70127-6 *(B. subtilis var amyloliquefaciens)* and 70127-7 (*Metarrhizium anisopliae*) products.
I have a request from Novozymes for BPPD to correct a registration notice for a pesticide (EPA Reg. No.70127-6) which contains *Bacillus subtilis var amyloliquefaciens* Strain FZB24 as the active ingredient. It was given unconditional registration under FIFRA Section (3(C)(5) on **01/20/2000.** It is called **TAE-Technical** on the transfer letter. BPPD's revised Notice of registration (02/12/2007) to your company with the EPA Reg. No. 70127-6 was incorrectly issued with the name TAE-Technical while containing the conditions of registrattion for the *Metarrhizium* F52 technical - called TAE-001 Technical Bioinsecticide, (EPA Reg.No. 70127-7)

TAE-022

70127-6 - ~~TAE-Technical~~ - *Bacillus subtilis var amyloliquefaciens* Strain FZB24
70127-7 - **TAE-001 Technical Bioinsecticide** - *Metarrhizium anisopliae* F52

What may have contributed to the confusion is the similarity in the two names. While we are amending the labels for Metarrhizium products, would you consider changing the name for the *Metarrhizium* technical? Also, have you submitted an updated label and CSF for 70127-6, the *B. subtilis* product? As discussed yesterday, as part of the amendments, I am preparing new registration notices updating your case for *Metarrhizium* and working with Susanne Cerrelli, who has been the RAL on the *B. subtilis* case to resolve the issues about the latter pesticides.

70127-9 - *Metarrhizium* F52 product
I looked at the submission you gave me yesterday for the new process for Metarrhizium technical. Our systems show that Andy Bryceland responded to your notification request to let you know that process modification cannot be submitted as a notification. Ibrahim has also looked at the submission and has informed me of the following deficiencies in the submission:

1. You have submitted a method to use selective media for detection of coliform bacteria but have not used Trypticase Soy Agar (TSA) medium or Brain Heart Infusion (BHI) meidum to detect general bacterial contamination and determine the level of contamination.
2. The types of fungal contamination are not identified.
3. The plates should be incubated for up to 48 rs to detect any slow-growing bacteria.
4. It is not clear if you are summarizing the results from a five batch analysis or if you are merely stating that this is the protocol your lab will follow to analyze the batches produced with the new manufacturing process. The Agency will require analyses of 5 batches to show that the new process does not result in higher levels of contamination than the previously reviewed manufacturing process.

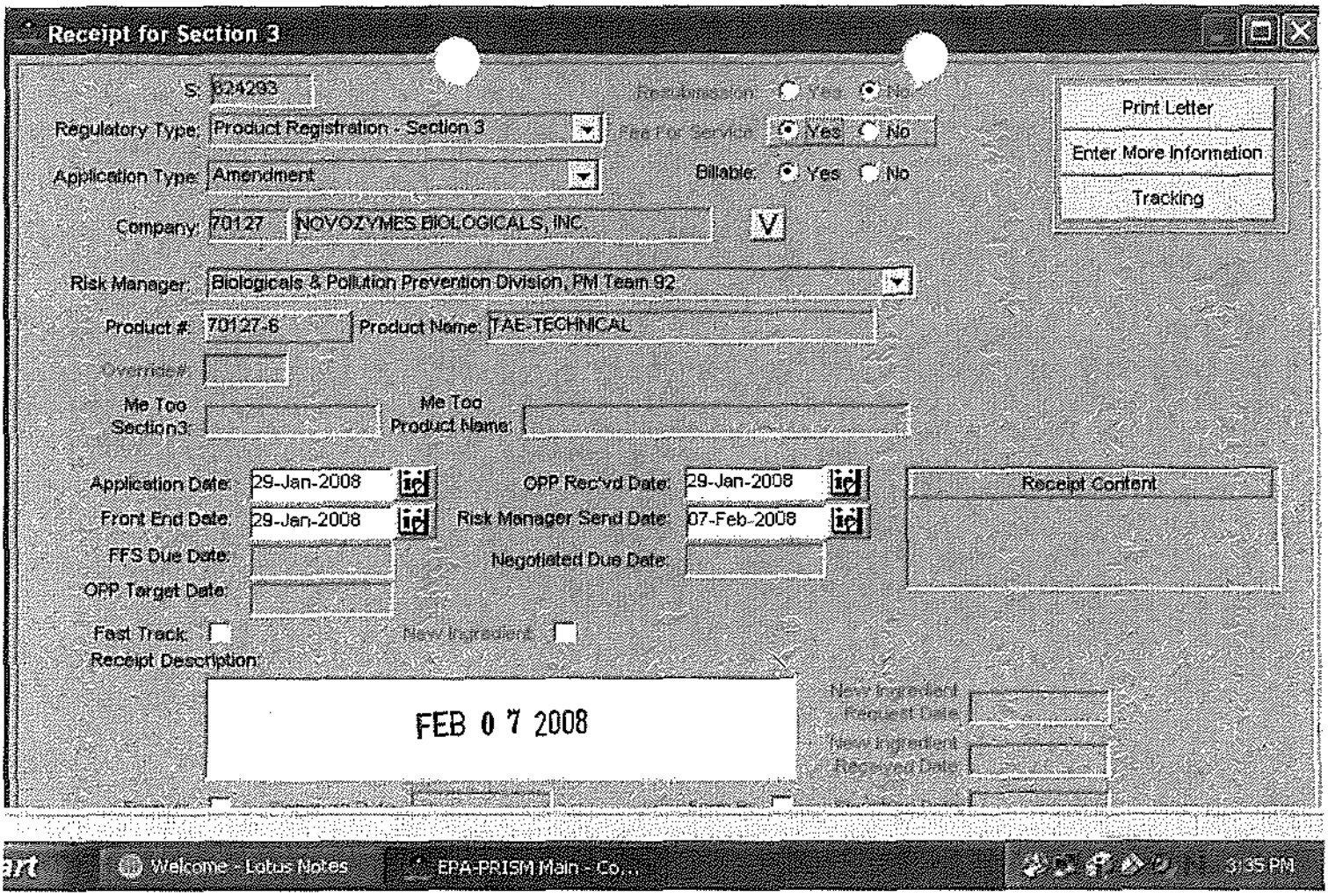
Conditions

key need to submit a new PRIA amendment

This amendment must be formatted in accordance with PR Notice 86-5 and will be assigned a code B 680 and will cost $ 4,410

680

Sincerely,
Shanaz Bacchus, Chemist



350: Shan

The company is requesting a corrected registration notice ("unconditional") for this product.

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

January 29, 2008

Mr. Leonard Cole
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504 P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Dear Leonard;

On behalf of our client, Novozymes Biologicals, Inc. (Novozymes) (5400 Corporate Circle, Salem, VA 24153), Exponent would like to provide you with a copy of a correction sent to Dr. Sheryl Reilly in the biopesticide division regarding the registration status of TAE-Technical (EPA Reg. Number 70127-6).

If you have any further questions please contact me via email at jmessina@exponent.com or via telephone at (202) 772-4932.

Best regards,

James Messina
Authorized Representative for
Novozymes Biologicals, Inc.

Enclosure

cc: Tom Schreier, Novozymes Biologicals, Inc.

Exponent

Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

January 29, 2008

Dr. Sheryl K. Reilly
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
US Environmental Protection Agency

Subject: Correction for Registration Status of TAE-Technical
(EPA Reg. Number 70127-6)

Dear Dr. Reilly;

On behalf of our client Novozymes Biologicals, Inc. (Novozymes) (5400 Corporate Circle, Salem, VA 24153), Exponent, Inc. is submitting a correction regarding TAE-Technical (EPA Registration Number 70127-6).

On January 20, 2000 the EPA issued an unconditional registration to Taensa, Inc. for TAE-Technical (EPA Registration Number 72098-6) containing the active ingredient *Bacillus subtilis* Strain FZB24. Please find a copy of this notice enclosed. Earth Biosciences then purchased Taensa, Inc. and all pesticide registrations. Earth Biosciences was then purchased by Novozymes Biologicals, Inc. in 2006. The EPA approved the transfer of Earth Biosciences' products (six containing the active ingredient *Metarhizium anisopliae* strain F52 and one containing *B. subtilis*) to Novozymes Biologicals on December 7, 2006. Please find a copy of this transfer letter enclosed. With the transfer to Novozymes Biologicals, the registration number for TAE-Technical was changed from 72098-6 to 70127-6.

When originally registered by Taensa, the *M. anisopliae* containing products were assigned conditional registrations due to outstanding efficacy data. However, the active ingredient for TAE-Technical is *B. subtilis,* was originally granted an unconditional registration. It appears that TAE-Technical was accidentally included in the extension request with the rest of the *M. anisopliae* products, and the mistake has persisted ever since.

Please find enclosed the following documents:

- EPA Notice of Unconditional Pesticide Registration (Jan. 20, 2000)
- Transfer of Pesticide Registrations and Data (Dec. 7, 2006)
- EPA Notice of Conditional Pesticide Registration (Feb. 12, 2007)

Please change the conditional Notice of Registration back to unconditional and issue a new Notice of Registration as soon as possible. Please forward a copy to my attention when it has been corrected.

If you have any further questions please contact me via email at jmessina@exponent.com or via telephone at (202) 772-4932.

Best regards,

James Messina
Authorized Representative for
Novozymes Biologicals, Inc.

Enclosures (3)

cc: Tom Schreier, Novozymes Biologicals, Inc.
Leonard Cole, USEPA

72098-6 1-20-2000

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7501W) 401 M St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
__X__ Registration
____ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
72098-6	JAN 20 2000

Term of Issuance: Unconditional

Name of Pesticide Product: TAE-Technical

Name and Address of Registrant (include ZIP Code):

Taensa Inc
26 Sherman Ct
P.O. Box 764
Fairfield, CT 06430

Note - Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been coveted by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit five(5) copies of the revised final printed labeling including the EPA Registration Number and Establishment Number before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division (7511C)

Signature of Approving Official:	Date:
	1-20-00

EPA Form 8570-6

2/

TAE-022 TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

	% w/w
ACTIVE INGREDIENT – *Bacillus subtilis var. amyloliquefaciens* Strain FZB24*.....	73.3%
OTHER INGREDIENTS	26.7%
Total	100.0%

* Contains 5.0 x 10^{11} Colony Forming Units ("CFU")/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

Causes substantial but temporary eye injury. Do not get in eyes. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available, by administering syrup of ipecac. If a person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF INHALED - Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.

EMERGENCY INFORMATION

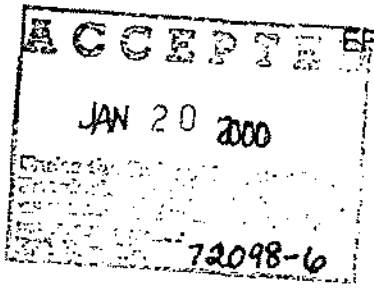
For spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Net Contents _____

Taensa, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430 U.S.A.



EPA Establishment Number _____
EPA Registration Number: 72098-A
Made in U.S.A.
Revision: 990208

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into product for the following use:

- For plant strengthening, growth enhancement and suppression of certain diseases

This product may be used to formulate products for any additional use(s) not listed on the TAE-022 Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: TAE-022 consists of living microbes. Store in a cool dry place. Do not freeze or expose to temperatures above 80° F. Opened packages should be closed tightly and stored in a cool dry place and used within one month.

PESTICIDE DISPOSAL: Unused TAE-022 Technical and wastes resulting from the use of this product may be disposed of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONTAINER DISPOSAL: Dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE

Taensa, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 7, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MR. THEODORE MELNIK
NOVOZYMES BIOLOGICALS, INC.
5400 CORPORATE CIRCLE
SALEM, VA 24153

Dear Mr. Melnik:

Subject: Transfer of Pesticide Registrations and Data From Company Number **72098** to Company Number **70127**

Pursuant to your request in your letter and transfer agreement of October 20, 2006 and subsequent information received on December 4, 2006, we have approved the transfer of the following registrations and data from **EARTH BIOSCIENCES INC.**, company number **72098** to **NOVOZYMES BIOLOGICALS, INC.**, company number **70127**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
BEETLEBALL TECHNICAL	72098-4	70127-4
TAEGRO	72098-5	70127-5
TAE-TECHNICAL	72098-6	70127-6
TAE-001 TECHNICAL BIOINSECTICIDE	72098-7	70127-7
TAENURE GRANULAR BIOINSECTICIDE	72098-8	70127-8
TICK-EX G	72098-12	70127-9
TICK-EX EC	72098-13	70127-10

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment

Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated October 20, 2006 and subsequent information received on December 4, 2006 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **NOVOZYMES BIOLOGICALS, INC.** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Evelyn Alston at (703) 305-5058.

Sincerely,

Kathryn S. Bouvé

Kathryn S. Bouvé, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR. TOM CORELL
EARTH BIOSCIENCES INC.
106 SOMERSET AVENUE
FAIRFIELD, CT 06824

EPA Reg. Number: 70127-6	Date of Issuance:
Term of Issuance: Conditional	

Name of Pesticide Product:
TAE-TECHNICAL

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.

3. This registration is registered under FIFRA § 3(c)(7)(C) because of outstanding data of your technical product.

Signature of Approving Official:	Date:
(See second page for signature)	FEB 12 2007

EPA Form 8570-6

5. You must submit the field efficacy data for the control of blacklegged ticks (Ixodes scapularis). Efficacy data must be developed for each specified public health pest. These product performance data must be submitted by December 31, 2007.

6. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

MATERIAL TO BE ADDED TO JACKET

REG #: 70127-6

Description: Formulation Amendment

if applicable, check all that are attached:		
☐	new stamped accepted label	Send to CSC
☒	new CSF	
☐	notification	
☐	other:	

Instructions:
Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Jeannine Kausch Date: 8/4/2009

Phone: (703) 347-8920 Division: BPPD

Formulation Amendment (#70127-6) - Approved 08-03-2009

Jeannine Kausch to: TASC (Tom Schreier) 08/04/2009 06:01 AM

Hi Tom,

The formulation amendment, which you submitted back in April for Taegro Technical (#70127-6), was approved yesterday. I've attached a courtesy copy of the acceptance letter below. A hard copy of this letter, along with a stamped copy of the CSF, will be sent to you via regular mail this afternoon. Please remember that this amendment was accepted based on the term that a 5-batch analysis will be submitted to the Agency by February 15, 2011.

Let me know if you have any questions or concerns.

Thanks,

Jeannine

Taegro Technical_Formulation Amendment_08-03-2009.pdf

AUG 0 3 2009

Mr. Thomas Schreier
Regulatory Affairs Manager
Novozymes Biologicals, Incorporated
5400 Corporate Circle
Salem, VA 24153

Re: Novozymes Biologicals, Incorporated; Taegro Technical
EPA Registration No. 70127-6
-Formulation amendment to move manufacturing site from Germany to Virginia, modify the lower certified limit for the active ingredient, and update the product name
Application Dated 04/03/2009
Decision #409510

Dear Mr. Schreier:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit a five-batch analysis from batches produced at the new manufacturing facility in Salem, Virginia by February 15, 2011 (in accordance with OPPTS Harmonized Guideline 885.1400).

2. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

The new confidential statement of formula (CSF) dated July 28, 2009 supersedes the previous CSF dated May 4, 2007 and will be filed in the Agency's records as the official CSF.

CONCURRENCES								
SYMBOL ▶	7511P	7511P						
SURNAME ▶	KAUSCH							
DATE ▶	08/03/2009	8/3/09						

Your release for shipment of the product with the amended formulation constitutes acceptance of these conditions. If you have any questions contact Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

A stamped copy of the CSF is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure (1):
-CSF dated July 28, 2009

ROUTING AND TRANSMITTAL SLIP Date: 08/03/2009

TO: *(Name, office symbol, room number, building, Agency)* Sheryl Reilly					
	Action		File		Note and Return
X	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		Concurrence

REMARKS

Jeannine -
Put this in accomps -
Thanks!
Sheryl

Product Name: Taegro Technical
Action Type: Formulation amendment to move manufacturing site from Germany to Virginia, modify the lower certified limit of the active ingredient (still within the original range), and update the product name
EPA Reg. No.: 70127-6
PRIA Due Date: August 27, 2009

**This formulation amendment arrived at the Agency without data. Since the registrant will need to begin production before submitting a 5-batch analysis (production will begin upon approval of this amendment and this is why no data were submitted with the original application), we decided to ask for the 5-batch analysis as a term of the amendment acceptance letter. After talking with the company representative about time needed to complete and submit the 5-batch analysis, they have been given approximately 18 months from the amendment letter acceptance date (i.e., February 2011) to fulfill the term.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: *(Name, org. symbol, Agency/Post)*	Room No.-- Bldg.
	S-8931
Jeannine Kausch	Phone
	(703) 347-8920

RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF
Jeannine Kausch to: TASC (Tom Schreier) 07/29/2009 11:03 AM

Hi Tom,

Thanks for submitting the new information. I'll look everything over and let you know if anything additional needs to be addressed. As I mentioned in a previous email, I am attaching a draft acceptance letter for the formulation amendment. Please just let me know if the time frame provided for submission of the 5-batch will work for Novozymes. I picked a date about 18 months from August.

Also, in looking through past documentation relating to this product, I found that I will have to process a label amendment, which has been in-house since February but has not yet been taken care of. In conjunction with this label, I can also get the registration notice reissued if it is needed...Is this the case? I noted a product name problem had occurred in the past with several products that currently are registered to Novozymes.

Regards,

Jeannine

Taegro Technical_Formulation_07-2009.doc

"TASC (Tom Schreier)" Hi Jeannine, The attached documents are... 07/28/2009 11:17:04 AM

From: "TASC (Tom Schreier)" <tasc@novozymes.com>
To: Jeannine Kausch/DC/USEPA/US@EPA
Date: 07/28/2009 11:17 AM
Subject: RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Jeannine,
The attached documents are being sent overnight and should arrive on Wednesday. Please let me know if anything needs to change.

Thanks for all of your help!!!

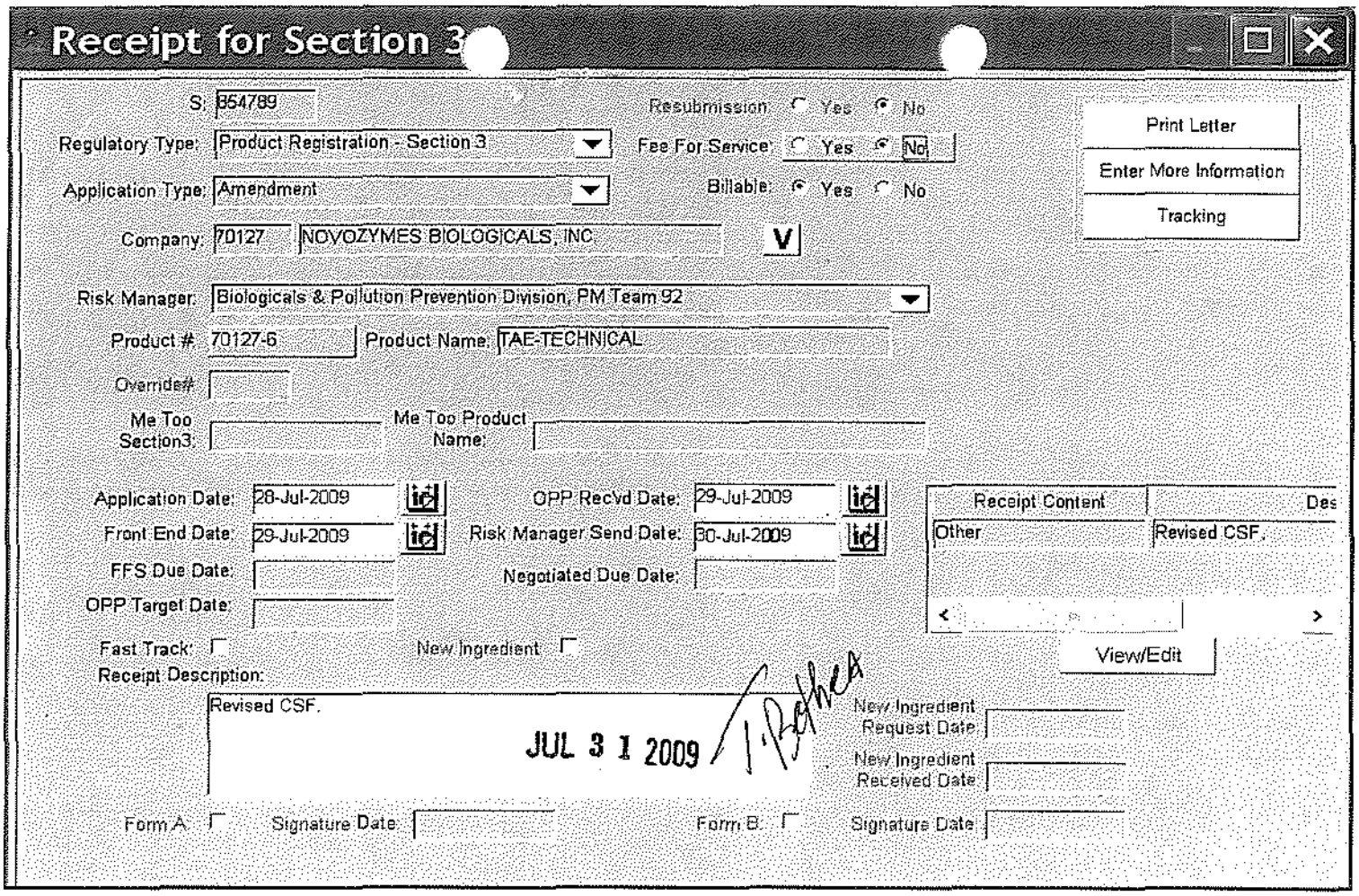
Tom

Best Regards
Tom Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 387-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

Novozymes Biologicals, Inc. (reg. no.:54-2042079). Registered address: Commonwealth Legal Service Corporation, 4701 Cox R, Glen Allen, VA 23060-6802, United States of America
This e-mail (including any attachments) is for the intended addressee(s) only


Receipt for Section 3
S: 854789
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 70127 NOVOZYMES BIOLOGICALS, INC.
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92
Product #: 70127-6
Product Name: TAE-TECHNICAL
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 28-Jul-2009
OPP Recvd Date: 29-Jul-2009
Front End Date: 29-Jul-2009
Risk Manager Send Date: 30-Jul-2009
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Other
Revised CSF.
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Revised CSF.
JUL 3 1 2009
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Pages 193-194 - *Claimed confidential by submitter*

Please read instructions on reverse before co. ting form. Form Approved. MB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 70127-6
2. EPA Product Manager: Sheryl Reilly
3. Proposed Classification: ☐ None ☐ Restricted
4. Company/Product (Name): Novozymes Biologicals /Taegro Technical
PM#: 92
5. Name and Address of Applicant *(Include ZIP Code)*:
Novozymes Biologicals Inc.
5400 Corporate Circle
Salem, VA 24153
☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Submission of revised CSF in accordance with Agency e-mails dated 13-21 July, 2009.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☒ Container
4. Size(s) Retail Container: 250 or 500 gal.
5. Location of Label Directions: ☒ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schreier, tasc@novozymes.com	Regulatory Affairs Mgr.	(540) 302-1186

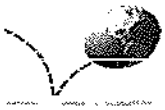
Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Thomas Schreier
3. Title: Regulatory Affairs Manager
4. Typed Name: Thomas Schreier
5. Date: 7/28/2009

EPA Form 8570-1 (Rev. 6-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy



Taegro Technical (#70127-6) - Allowed Time For Follow-Up Data Submission

Jeannine Kausch to: Sheryl Reilly 07/21/2009 01:56 PM

Hi Sheryl,

I have a PRIA action for Taegro Technical (EPA Reg. No. 70127-6; ai: *Bacillus subtilis* var. *amyloliquefaciens*), which will be due in mid-August. This is a formulation amendment where the registrant has requested to move their manufacturing facility from Germany to Virginia and update the product name. However, although this was considered a PRIA action, it also came in with no data. The registrant is aware that they need to submit a 5-batch analysis with production batches from their new site, but they will not start producing these new batches until the manufacturing facility switch is approved by the Agency (which is why they did not submit the relevant data with this particular action).

Alan inquired several weeks ago, during one of the management meetings I believe, and confirmed that we could approve the registrant's request provided no other issues came to light. He also established that we would need to ask for the 5-batch analysis as a term in the acceptance letter.

Question: The registrant has proposed that they could get the Agency the 5-batch analysis within 18 months of this amendment's approval. Do you believe this is acceptable (Alan wanted me to verify with you)? For some registrations where manufacturing has not yet been initiated, which would be applicable in this case, we have allowed up to 30 months (*Aspergillus flavus*) for submission of a 5-batch analysis.

Thanks,

Jeannine

RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Jeannine Kausch to: TASC (Tom Schreier) 07/21/2009 09:28 AM

Hi Tom,

Thanks for the prompt response to my questions. I will begin drafting the acceptance letter for the formulation amendment based on the information that you have provided me. Once I complete the draft, I will send it through you just to confirm that the time frame outlined for the 5-batch analysis is acceptable to Novozymes. Prior to sending anything up for management approval, I will have to have the revised CSF in hand; however, I don't see a problem if you send this information to the Agency when you get back from your travel.

Thanks,

Jeannine

"TASC (Tom Schreier)" Hi Jeannine, We have updated the CSF an... 07/20/2009 06:38:18 PM

From: "TASC (Tom Schreier)" <tasc@novozymes.com>
To: Jeannine Kausch/DC/USEPA/US@EPA
Date: 07/20/2009 06:38 PM
Subject: RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Jeannine,
We have updated the CSF and have placed the ingredient into a culture collection last week. I had to travel prior to being able to send the revised CSF into you. I will be back next week and you should have the document on Tuesday or Wednesday. We will be able to complete 5 batches within 18 months. I would call but am unable to get reception. If you require the CSF sooner, I will be in France on Thursday of this week and can send it by e-mail then.

Thanks for your help.

Tom

Best Regards
Tom Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Monday, July 20, 2009 12:54 PM
To: TASC (Tom Schreier)
Subject: RE: Taegro Technical (EPA Reg., No. 70127-6) - Revised CSF

Hi Tom,

I am trying to get a quick update on this action (from your end) as I would like to begin drafting the acceptance letter for your request; however, I still need some key information that has not yet been provided.

1) Following up on one of the questions that you posed about culture collection deposit...Does Novozymes currently have the active ingredient for Taegro Technical deposited in a recognized culture collection? If not, I will include this as a requirement (along with the request to provide documentation and a revised CSF) in the amendment letter. Furthermore, if this active ingredient is not currently on deposit, is this something that could be accomplished within 45 days of an acceptance letter?

2] I still need you to provide me with a reasonable estimation of how long your company needs to produce 5 batches, complete the analyses of these batches, and provide EPA with the relevant information. A due date will be established in the acceptance letter.

3) Status of the revisions requested on the CSF?

I would like to attempt to get your action completed well in advance of the PRIA due date, which is why I keep pressing for the additional information.

Thanks,

Jeannine

From: Jeannine Kausch/DC/USEPA/US

To: "TASC [Tom Schreier)" <tasc@novozymes.com>

Date: 07/15/2009 05:31 PM

Subject: RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Tom,

Thanks for the reply to my initial emails. To answer the questions that you posed below:

#1) You do not have to deposit the active ingredient prior to revising the CSF (for this action). However, if you do not currently have this

active ingredient in a recognized culture collection, I will add the requirement to do so within a particular amount of days in the acceptance letter for your pending formulation amendment. When the active ingredient is deposited into a culture collection, the requirement would ask the company to provide us with documentation showing the identification number and place of deposit. Concurrently, you would need to submit a revised CSF indicating the new culture collection identification number.

#2) You can keep the new revised certified limit (lower) for this product as it is still within the previously approved range (and it makes sense based on the percentage of impurities at the upper certified limit). When you resubmit this revised CSF back to the Agency, be sure to include your short justification for the change in supporting documentation or the cover letter. Also keep in mind that this new lower limit would become legally binding upon acceptance of this CSF.

**Also, please be sure that this change would not affect the lower limit of activity provided near the signature block at the bottom of the CSF.

Hopefully, I've addressed your questions but should you need further guidance, let me know!

Thanks,

Jeannine

From: "TASC (Tom Schreier)" <tasc@novozymes.com>

To: Jeannine Kausch/DC/USEPA/US@EPA

Date: 07/15/2009 04:23 PM

Subject: RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi,
In #1 below, a.i. was changed to air and went out before I could stop it.

Best Regards
Tom Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

23060-6802, United States of America
This e-mail (including any attachments) is for the intended addressee(s) only and may contain confidential and/or proprietary information protected by law. You are hereby notified that any unauthorized reading, disclosure, copying or distribution of this e-mail or use of information herein is strictly prohibited. If you are not an intended recipient you should delete this e-mail immediately. Thank you.

-----Original Message-----
From: TASC (Tom Schreier)
Sent: Wednesday, July 15, 2009 4:21 PM
To: 'Kausch.Jeannine@epamail.epa.gov'
Subject: RE: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Jeannine,

I am redoing the CSF now but have two questions:

1. If the air. is not in a culture collection at this time, must we deposit it prior to completing the CSF?
2. The lower limit was raised to match the total of the maximum amount of impurities. We can keep it at the previous number if that would be better. Do you have a preference?

Let me know what you want us to do.

Thanks,
Tom

Best Regards
Tom Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

Novozymes Biologicals, Inc. (reg. no.:54-2042079). Registered address: Commonwealth Legal Service Corporation, 4701 Cox R, Glen Allen, VA 23060-6802, United States of America
This e-mail (including any attachments) is for the intended addressee(s) only and may contain confidential and/or proprietary information protected by law. You are hereby notified that any unauthorized reading, disclosure, copying or distribution of this e-mail or use of information herein is strictly prohibited. If you are not an intended recipient you should delete this e-mail immediately. Thank you.

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [
mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Tuesday, July 14, 2009 10:41 AM
To: TASC (Tom Schreier)
Subject: Fw: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Tom,

My apologies for the follow-up email and any confusion I might have caused, but please disregard my first comment below speaking to resubmission of Taegro Technical's label. I was given a bunch of documentation and have found your original request from November 2008. I will take care of your request associated with the label as soon as possible. I would ask that you still address points #2 and #3 below, so that I may progress forward with your formulation amendment request.

Thanks,

Jeannine
----- Forwarded by Jeannine Kausch/DC/USEPA/US on 07/14/2009 10:34 AM -----

From: Jeannine Kausch/DC/USEPA/US

To: "TASC (Tom Schreier)" <tasc@novozymes.com>

Date: 07/13/2009 03:25 PM

Subject: Taegro Technical (EPA Reg. No. 70127-6) - Revised CSF

Hi Tom,

I've been assigned to see your request for a revised CSF (w/ updated name and manufacturing facility), with a PRIA due date of 08/27/2009, through the process. Although this is a unique request in that it is considered a PRIA amendment (B680) yet the submission did not come in with any data, I've talked with my team leader, Alan Reynolds. He mentioned that we could approve your request and require the analysis of 5 batches as a condition, and that this would be explained in the acceptance letter. However, before I send an acceptance letter forward for management approval, I will need you to initiate a few items and answer one question.

1) In the cover letter accompanying the B680 amendment, you mention that a label was submitted in November 2008 to reflect the name change that will also be seen on this new CSF. I see indication that something was submitted in 2008, but it does not look like the Agency ever approved (or even took action) on what was submitted. Would you please resubmit your labels, for this product only, as a fast track amendment (non-PRIA) and describe what you would like to change on this technical product label? I still work on fast track labels and will ensure that this amendment gets processed and completed in a timely manner.

2) With your amendment submission, you enclosed a Confidential Statement of Formula, which seems to be correct for the most part. However, I will you need to make a few minor corrections and resubmit a revised version as soon as possible (no CBI is revealed in this email because of the unsecured means of communication):

In box #5, please change "Sheryl Reilly, Ph.D." to "Sheryl Reilly / 92."
In box #10 for the active ingredient, can you indicate the culture deposit number?
In box #10 and for the last "ingredient," please indicate "CAS Number: NA" as is done for the other ingredients.
For both of the impurities, please do not include a lower limit (http://www.epa.gov/pesticides/biopesticides/regtools/biopest_csf.pdf - see page 10). Please just leave a dash in this space for both of these values as was done on the CSF dated May 4, 2007.
Please ensure that all values in columns 13a, 13b, 14a, 14b (except for the lower limits of the impurities) are taken out to the tenths place.
Please provide a brief justification for the change in the lower certified limit for the active ingredient.
Please ensure the CSF is resigned, dated, and sent back to the Agency to my attention along with the justification mentioned in the previous bullet.

3) Please provide me with a reasonable estimation of how long your company needs to produce 5 batches, complete the analyses of these batches, and provide EPA with the relevant information (e.g., 1.5 years). A solid date will go into the acceptance letter, which is why I am asking you to provide a reasonable time frame. You can answer this question via email.

Thanks for your assistance and cooperation with the above matters! Let me know if you have any questions.

Jeannine

703-347-8920

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

File Copy

May 11, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-409510
EPA File Symbol or Registration Number: 70127-6
Product Name: TAE-TECHNICAL
EPA Receipt Date: 06-Apr-2009
EPA Company Number: 70127
Company Name: NOVOZYMES BIOLOGICALS, INC.

THEODORE MELNIK
NOVOZYMES BIOLOGICALS, INC.
5400 CORPORATE CIRCLE
SALEM, VA 24153

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

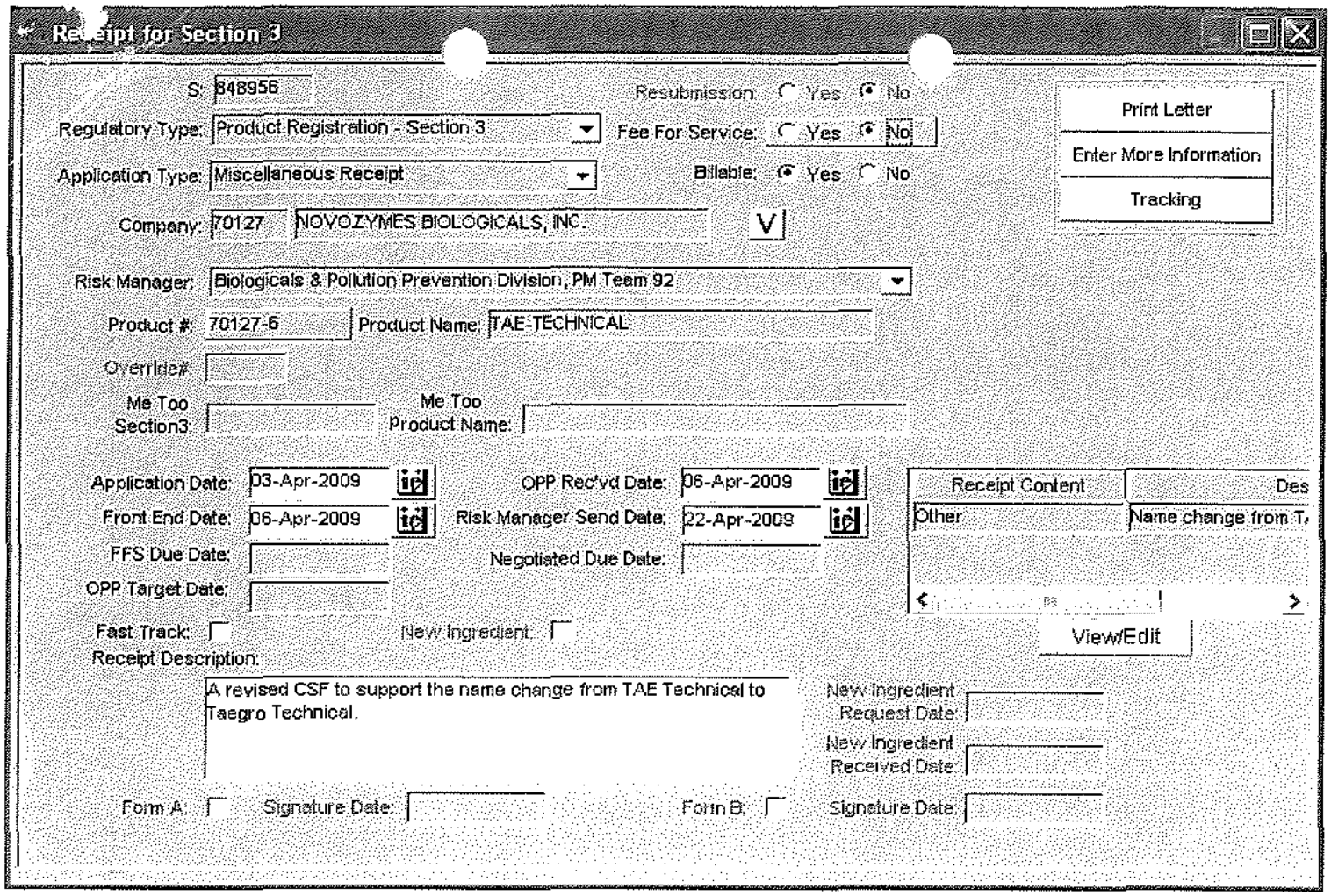
AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division



JJ - pls. change this to a B680 - thank you -
Sheryl Reilly

(PM 56957)

Dana -
Please assign
as a CSF amendment
to Jeannine Kausch.
Code = 345
Thank you!
Sheryl Reilly

AIO - Jeannine
MAY 7 2009

Copy to O'Malley 4/6/09

novozymes®
Rethink Tomorrow

April 3, 2009

Taegro Technical EPA Registration No. 70127-6, Submission of Revised CSF

Shaiaz Bacchus
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7504P)
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Bacchus,

In November 2008 Novozymes submitted a request for a name change and submitted new labels for the product TAE Technical, EPA Registration Number 70127-6. The new name for the product is Taegro Technical. At this time Novozymes is pleased to submit a new CSF reflecting the new name.

In addition to changing the name of the product Novozymes is moving the manufacturing site of the product from Germany to the Novozymes Facilities located in Salem, Virginia. All facets of the production of Taegro other than location remain unchanged. Once the new manufacturing location is approved and production initiated, Novozymes will submit the results of the analysis of 5 batches of product to the US EPA.

Please find enclosed the following documents:

- One copy of EPA form 8570-1, Application for Pesticide.
- On copy of EPA form 8570-4, Confidential Statement of Formula dated 5/4/07.
- Two copies of EPA form 8570-4, Confidential statement of Formula dated 4/2/09.
- One copy of the confirmation of the payment of the PRIA fee.

If you have any questions or need any assistance in this matter, please contact me in Roanoke VA at (540) 302-1186 or by e-mail at: tasc@novozymes.com.

Sincerely,

Thomas Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
Phone: 800 859 2972 • 540 389 9361 • Fax: 540 389 2688
www.novozymes.com/microorganisms

Please read instructions on reverse before c ting form. Form Approved. OMB No. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Shanaz Bacchus	☐ None ☐ Restricted
4. Company/Product (Name) Novozymes Biologicals /Taegro Technical	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*
Novozymes Biologicals Inc.
5400 Corporate Circle
Salem, VA 24153
☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. A revised CSF to support the name change from TAE Technical to Taegro Technical is being submitted at this time.
2. In addition to the proposed name change the site of manufacture is also be changed.
3. Ms. Bacchus has indicated that this action was to be assigned PRIA code B680, Label amendment requiring data submission.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistent Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container	250 or 500 gal.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☒ Lithograph / Paper glued / Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schreier, tasc@novozymes.com	Regulatory Affairs Mgr.	(540) 302-1186

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Thomas Schreier	Regulatory Affairs Manager
4. Typed Name	**5. Date**
Thomas Schreier	4/3/2009

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24VCMC1R
Agency Tracking ID: 74067947580
Transaction Date and Time: 04/03/2009 09:23 EDT

Payment Summary

Address Information		Account Information		Payment Information	
Account Holder Name:	Thomas Schreier	**Card Type:**	Master Card	**Payment Amount:**	$4,410.00
Billing Address:	5400 Corporate Cir.	**Card Number:**	**********4004	**Transaction Date and Time:**	04/03/2009 09:23 EDT
Billing Address 2:		**Decision Number:**			
City:	Salem	**Registration Number:**	70127-6		
State / Province:	VA				
Zip / Postal Code:	24153				
Country:	USA				

Shanaz Bacchus/DC/USEPA/US

08/13/2008 08:26 AM

To Linda Roberts/DC/USEPA/US@EPA
cc Susanne Cerrelli/DC/USEPA/US@EPA
bcc
Subject Fw: B. subtilis Products - Taegro

Linda, please check among our DERs databases to see if there are any for the products listed below. I am copying Susanne in case it is one of her cases.
If either of you find the DERs, please send them on to Tom, and let me know that the task is complete. If not, can we find the DERs?
Thanks for your help,
shawn
Washington D.C. 20460
Phone: 703-308-8097

.....

----- Forwarded by Shanaz Bacchus/DC/USEPA/US on 08/13/2008 08:20 AM -----

"TASC (Tom Schreier)" <tasc@novozymes.com>

08/12/2008 05:33 PM

To Shanaz Bacchus/DC/USEPA/US@EPA
cc
Subject RE: Met 52 Products - Taegro

Ms. Bacchus,
The need for DERs for New York is to support the registration of the pesticide Bacillus subtilis var. Amyloliquefaciens Strain FZB24. The current Novozymes Biologicals Inc. registration numbers are 70127-5 and 70127-6. The original EPA registration numbers were 72098-5 and 72098-6 and the company name was Earth Biosciences Inc.

00644

The MRID numbers are 447581-21 through 447581-27. DERs for these studies

I would appreciate any help that you can provide.

Thank you,
Tom

- ARCHIVE
- IHAD

Best Regards
Tom Schreier
Regulatory Affairs Manager

Novozymes Biologicals, Inc.
5400 Corporate Circle

Salem VA 24153 United States
Phone: +1 540 302-1186
Mobile: +1 540 556-7086
E-mail: tasc@novozymes.com

Novozymes Biologicals, Inc. (reg. no.:54-2042079). Registered address: Commonwealth Legal Service Corporation, 4701 Cox R, Glen Allen, VA 23060-6802, United States of America
This e-mail (including any attachments) is for the intended

addressee(s) only and may contain confidential and/or proprietary information protected by law. You are hereby notified that any unauthorized reading, disclosure, copying or distribution of this e-mail or use of information herein is strictly prohibited. If you are not an intended recipient you should delete this e-mail immediately. Thank you.

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Tuesday, August 12, 2008 2:47 PM
To: TASC (Tom Schreier)
Subject: RE: Met 52 Products - Taegro

I got your voicemail and looked at the letter in the FOIA email. The
studies cited are 447581-21 thru -27. Do you need DERS for these studies? The DERs I have are in the 448447-20 series which were submitted more recently (eviewed between 2001 - 2003).

If you send me the following, I'll look around for the reviews.
Registration #,
PC Code and
MRID #s

However, if they are from a product registered to a previous company,
the jackets and DERs may not be readily available.

Sincerely,
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511P)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

6B 3 3

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 70127-6

Send to SIG: check box ☑

This material is:

- ☐ New stamped-accepted label
- ☑ New CSF
- ☑ Notification
- ☐ Final Printed Label
- ☐ Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Andrew Bryceland

Phone: 305-6928 Division: BPPD

Date: 5/22/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Novozymes Biologicals, Inc.
c/o Carrie Daniels
Exponent
1730 Rhode Island Avenue
Suite 1100
Washington, D.C. 20036

Subject: Product Name: TAE-022 Technical
EPA Reg. No: 70127-6
Application for Notification Dated: May 5, 2007

Dear: Ms. Daniels:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the Confidential Statement of Formula, dated 5/4/07, submitted with this application will be placed accordingly in our records.

Questions concerning this action should be directed to Andrew C. Bryceland at (703)305-6928 or email at brycceland.andrew@ep.gov.

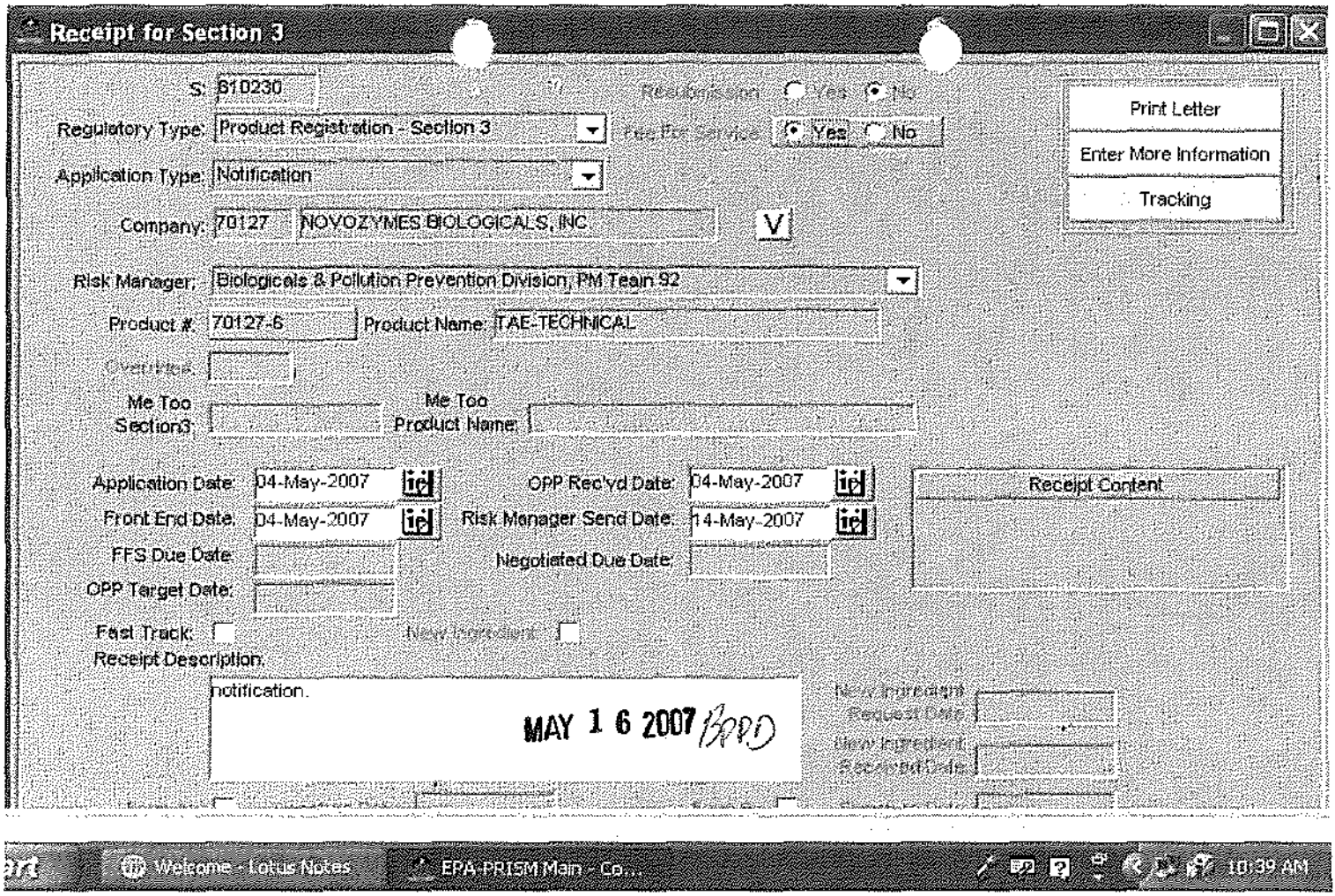
Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES								
SYMBOL	7511P							
SURNAME	Bryceland							
DATE	5/22/07							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY



Andy
332

AIO - Andy
MAY 21 2007
sdh

Exponent
1730 Rhode Island Ave., NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

May 4, 2007

Mr. Leonard Cole
Microbial Pesticides Branch
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7504P)
Document Processing Desk (NOTIF)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Subject: Notification Submission to Update Registrant Information on Basic Confidential Statement of Formula
TAE-022 Technical, EPA Reg. No. 70127-6

Dear Mr. Cole:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, VA 24153, EPA Company Number 70127), Exponent, Inc. is submitting a notification pursuant to PR Notice 98-10 to update the registrant information listed on the Basic Confidential Statement of Formula for the technical product TAE-022 Technical, EPA Registration Number 70127-6. In support of this action please find enclosed the following documents:

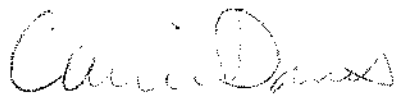
- Cover letter;
- Completed 8570-1 form;
- Updated Basic Confidential Statement of Formula (2 copies); and
- Copy of previously approved Basic Confidential Statement of Formula.

Novozymes recently acquired the registration for TAE-022 Technical from Earth BioSciences and is updating the CSF to reflect Novozymes as the registrant.

This notification is consistent with the provisions of the PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have questions regarding the above information, please contact me via telephone at (202) 772-4916 or via email at cdaniels@exponent.com.

Sincerely,



Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures (4)

cc: Shawn Semones, Novozymes Biologicals, Inc.
James Messina, Exponent

Please read instructions on reverse before con, ng form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-6	Leonard Cole	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Novozymes Biologicals, Inc. / TAE-022 Technical	BPPD	

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Mo Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of an Updated Basic Confidential Statement of Formula pursuant to PR Notice 98-10.

NOTIFICATION
Received But Not Reviewed

Section - III

Date: MAY 22 2007

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	Initial: AKB
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Metal [ ] Plastic [ ] Gloss [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
___ Label [ ] Container		

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Authorized Representative	202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingliy false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Carrie Daniels	Authorized Representative
4. Typed Name	5. Date
Carrie Daniels	5/4/07

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 7, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MR. THEODORE MELNIK
NOVOZYMES BIOLOGICALS, INC.
5400 CORPORATE CIRCLE
SALEM, VA 24153

Dear Mr. Melnik:

Subject: Transfer of Pesticide Registrations and Data From Company Number **72098** to Company Number **70127**

Pursuant to your request in your letter and transfer agreement of October 20, 2006 and subsequent information received on December 4, 2006, we have approved the transfer of the following registrations and data from **EARTH BIOSCIENCES INC.**, company number **72098** to **NOVOZYMES BIOLOGICALS, INC.**, company number **70127**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
BEETLEBALL TECHNICAL	72098-4	70127-4
TAEGRO	72098-5	70127-5
TAE-TECHNICAL	72098-6	70127-6
TAE-001 TECHNICAL BIOINSECTICIDE	72098-7	70127-7
TAENURE GRANULAR BIOINSECTICIDE	72098-8	70127-8
TICK-EX G	72098-12	70127-9
TICK-EX EC	72098-13	70127-10

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment

Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated October 20, 2006 and subsequent information received on December 4, 2006 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **NOVOZYMES BIOLOGICALS, INC.** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Evelyn Alston at (703) 305-5058.

Sincerely,

Kathryn S. Bouvé

Kathryn S. Bouvé, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR. TOM CORELL
EARTH BIOSCIENCES INC.
106 SOMERSET AVENUE
FAIRFIELD, CT 06824

Pages 219-228 - *Confidential Statements of Formula may be entitled to confidential treatment*